

Statement of Facts

- Patentees filed Irish Application No. S1999/0016 (the "Irish Application") on January 11, 1999.

- Patentees filed PCT/IE00/00004 (the "PCT Application") on January 11, 2000, claiming benefit from the "Irish Application."

- Patentees filed the present application/patent (*i.e.*, US Ser. No. 09/902,287 (now US 7,069,089)) on July 10, 2001. The present application/patent is a continuation of the PCT Application.

- Along with the present application/patent, patentees filed an unsigned declaration that claimed the benefit of priority of the Irish Application and noted that the present application/patent is a continuation of PCT Application. *See Exhibit A.*

- In response to a Notice of Missing Parts, the patentees filed a signed copy of the declaration on October 26, 2001. *See Exhibit B.*

- The PTO acknowledged the claim of priority in an Office Action dated September 12, 2003, where it stated "Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Ireland on Jan 11, 1999. It is noted, however, that applicant has not filed a certified copy of the S990016 application as required by 35 U.S.C. 119(b)." *See Exhibit C.*

- On March 11, 2004, patentees amended the specification of the present application/patent to include a reference to the priority claim. *See Exhibit D.* Specifically, patentees stated "This application is a continuation application of PCT/IE00/00004, filed on January 11, 2000 which claims the benefit of priority to Irish Application No. S1999/0016, filed on January 11, 1999.

- On July 30, 2004, patentees provided the PTO with a certified copy of the Irish Application as an attachment filed on that same date. For the PTO's convenience, Applicants have attached hereto another certified copy of the Irish Application. *See Exhibit H.*

- The PTO "Verified and Acknowledged" the claim of priority in a Bibliographic Data Sheet, which was originally filed along with the present application/patent on July 10, 2001. *See Exhibit E.*

- On May 12, 2006, patentees filed US Ser. No. 11/434,436 ("child application"), which is a divisional of the present application/patent. Patentees stated on the Utility Patent Application Transmittal that the child application is a divisional of the present application/patent. *See Exhibit F.*

- Along with the child application, patentees filed a copy of the declaration from the present application/patent, which claimed that the present application/patent is a continuation of the PCT Application and claims priority to the Irish Application.

- On June 9, 2006, the PTO issued a Filing Receipt in the child application. *See Exhibit G.* Under "Domestic Priority data as claimed by applicant" the PTO stated "This application is a DIV of 09/902,287 07/10/2001 PAT 7,069,089." Under "Foreign Applications" the PTO listed "IRELAND S990016 01/11/1999" and "IRELAND PCT/IE00/00004 01/11/2000."

- On June 4, 2009, patentees filed a Petition Under 37 CFR 1.38(a)(3) To Accept Unintentionally Delayed Claim on Priority Under 37 CFR 1.78(a)(2) And (5) ("First Petition"). In the First Petition, patentees noted, as they do here, that "on July 30, 2004, patentees provided the PTO with a certified copy of the Irish Application."

- On August 3, 2009, the PTO issued a Decision on Petition Under 37 CFR 1.78(a)(3) ("Decision"), dismissing the First Petition stating that it failed to meet the requirement that "the reference required by 35 U.S.C. §120 and 37 CFR 1.78(a)(2)(i) of the prior-filed application, unless previously submitted." The Decision also noted that a Certificate of Correction and a Power of Attorney form must be submitted.

Remarks

MPEP 201.11(III)(D) states: "If an applicant includes a benefit claim in the application but not in the manner specified by 37 CFR 1.78(a) (e.g., if the claim is included in an oath or declaration or the application transmittal letter) within the time period set forth in 37 CFR 1.78(a), the Office will not require a petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) to correct the claim if the information concerning the claim was recognized by the Office as shown by its inclusion on the filing receipt."

Here, patentees, along with the present application/patent, filed a declaration that included a claim to the benefit of priority of the Irish Application and noted that the present application/patent is a continuation of PCT Application. The Office never issued a filing receipt, but it did recognize the priority claim. In fact, the patent issued with the following text:

“CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of PCT/IE00/00004, filed on Jan. 11, 2000 which claims the benefit of priority to Irish Application No. S1999/0016, filed on Jan. 11, 1999.”

Moreover, the Filing Receipt for the child application acknowledges the chain of title going back to the Irish Application.

In other words, patentees included a benefit claim within the time period set forth in 37 CFR 1.78(a), but because no filing receipt was ever issued for the case, patentees are forced to file this petition. Because the PTO has repeatedly accepted the patentee’s claim for priority, and even included it in the issued patent, the granting of this petition should be a mere formality.

Patentees state that the entire delay between the date the claim was due under 37 C.F.R. 1.78(a)(2)(ii) and that date the claim was filed was unintentional.

Conclusion

As summarized below, this Petition meets each of the requirements of 37 C.F.R. 1.78(a)(3):

“(i) The reference required by 35 U.S.C. 120 and paragraph (a)(2) of this section to the prior-filed application, unless previously submitted;” [The patentees previously submitted a certified copy of the Irish Application to the PTO on July 30, 2004 along with an office action response of that same date. A copy of the office action response and another certified copy of the Irish Application is attached hereto as Exhibit H. A certified copy of the PCT Application is attached hereto as Exhibit I.]

“(ii) The surcharge set forth in § 1.17(t); and” [A check for the appropriate amount accompanies this Petition.]

“(iii) A statement that the entire delay between the date the claim was due under paragraph (a)(2)(ii) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.” [See statement above that “Patentees state that the entire delay between the date the claim was due under 37 C.F.R. 1.78(a)(2)(ii) and that date the claim was filed was unintentional.”]

As the Decision also requires, the patentees are concurrently filing a Certificate of Correction. See *Exhibit K*. Patentees are also re-filing a Power of Attorney that had been filed in this case on August 2, 2007, but was not entered onto the record. See *Exhibit J*.

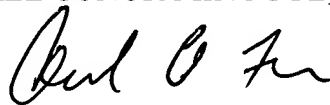
Based on the foregoing, patentees respectfully request that its claim to priority to the Irish application be perfected.

Respectfully submitted,

MICHAEL CONOR MINOGUE, *et al.*

Date: March 4, 2010

By: _____



ARMANDO A. FLORES
Reg. No. 41,754
Customer No. 23973
DRINKER, BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
Tel: (215) 988-2819
Fax: (215) 988-2757

EXHIBIT A



DECLARATION FOR PATENT APPLICATION (JOINT OR SOLE)

(Under 37 CFR § 1.63; with Power of Attorney)

FROMMER LAWRENCE & HAUG LLP

660057-2005

As a below named inventor, I hereby declare that:

This declaration is a continuation type declaration.

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

AN ELECTROTHERAPY DEVICE AND METHOD

the specification of which

X is attached hereto.

was filed on _____ as International Application Serial No. _____
with amendment(s) through _____ (if applicable, give dates).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s) (list additional applications on separate page):

Number:
S990016

Country:
Ireland

Filed (Day/Month/Year):
11 January 1999

Priority Claimed:

Yes **No**
x

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT International Application(s) designating The United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior PCT Application(s) (list additional applications on separate page):

Appln. Ser. Number:

PCT/IE00/00004

International Filing Date:

11 January 2000

Status (pending, abandoned):

Pending

I hereby appoint GORDON KESSLER, Registration No. 38,511 or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and specify that all communications about the application are to be directed to the following correspondence address:

GORDON KESSLER, Esq.
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151

Direct all telephone calls to:
(212) 588-0800
to the attention of:
GORDON KESSLER

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR(S)

Signature: _____

Date: _____

Full name of sole or first inventor:

MICHAEL CONOR MINOGUE

Residence:

Croshua, Kinvara
County Galway; Ireland

Citizenship:

Ireland

[Similarly list additional inventors on separate page]

Post Office Address(es) of inventor(s):

Note: In order to qualify for reduced fees available to Small Entities, each inventor and any other individual or entity having rights to the invention must also sign an appropriate separate "Verified Statement (Declaration) Claiming [or Supporting a Claim by Another for] Small Entity Status" form [e.g. for Independent Inventor, Small Business Concern, Nonprofit Organization, individual Non-Inventor].

00017087

DECLARATION FOR PATENT APPLICATION (JOINT OR SOLE)

(Under 37 CFR § 1.63; with Power of Attorney)

FROMMER LAWRENCE & HAUG LLP

660057-2005

ADDITIONAL INVENTORS

Signature: _____

Date: _____

Full name of 2nd joint inventor (if any): **MICHAEL LOUIS CROWE**

Residence: **65 Beech Park Road**

Dublin 18, Ireland

Citizenship: **Ireland**

Signature: _____

Date: _____

Full name of 3rd joint inventor (if any):

Residence:

Citizenship:

00017087

EXHIBIT B

COPY OF PAPERS
ORIGINALLY FILED

DECLARATION FOR PATENT APPLICATION (JOINT OR SOLE)
(Under 37 CFR § 1.63; with Power of Attorney)
FROMMER LAWRENCE & HAUG LLP

660057-2005

As a duly named inventor, I hereby declare that:
This declaration is a continuation type declaration.

My residence, post office address and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below)
of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

AN ELECTROTHERAPY DEVICE AND METHOD

the specification of which

is attached hereto.

☒ was filed on July 10, 2001 as U.S. Application Serial No. 09/902,287
with amendment(s) through _____ (if applicable, give dates).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s) (list additional applications on separate page):

Number:
S990016

Country:
Ireland

Filed (Day/Month/Year):
11 January 1999

Priority Claimed:

Yes No
x

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT International Application(s) designating The United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior PCT Application(s) (list additional applications on separate page):

Appln. Ser. Number:
PCT/E00/00004

International Filing Date:
11 January 2000

Status (pending, abandoned):
Pending

I hereby appoint GORDON KESSLER, Registration No. 38,511 or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and specify that all communications about the application are to be directed to the following correspondence address:

GORDON KESSLER, Esq.
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151

Direct all telephone calls to:
(212) 588-0800
to the attention of:
GORDON KESSLER

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR(S)

Signature:

Full name of sole or first inventor:

Residence:

Citizenship:

MICHAEL CONOR MINOGUE
Croshua, Kinvara
County Galway, Ireland
Ireland

Date: OCT 15 2001

[Similarly list additional inventors on separate page]

Post Office Address(es) of inventor(s):

Note: In order to qualify for reduced fees available to Small Entities, each inventor and any other individual or entity having rights to the invention must also sign an appropriate separate "Verified Statement (Declaration) Claiming for Supporting a Claim by Another for Small Entity Status" form [e.g. for Independent Inventor, Small Business Concern, Nonprofit Organization, individual Non-Inventor].

00032315

DECLARATION FOR PATENT APPLICATION (JOINT OR SOLE)
(Under 37 CFR § 1.63; with Power of Attorney)
FROMMER LAWRENCE & HAUG LLP

660057-2005

ADDITIONAL INVENTORS

Signature: _____

Full name of 2nd joint inventor (if any):

Residence:

Citizenship:

Michael Louis Crowe
MICHAEL LOUIS CROWE
65 Beech Park Road
Dublin 18, Ireland
Ireland

Date: Oct. 16th 2001

Signature: _____

Full name of 3rd joint inventor (if any):

Residence:

Citizenship:

Date: _____

EXHIBIT C



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,287	07/10/2001	Michael Conor Minogue		8694

20999 7590 09/12/2003
FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/12/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary

Application No.

09/902,287

Applicant(s)

MINOGUE ET AL

Examiner

Kristen L Droesch

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION*Priority*

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Ireland on Jan 11, 1999. It is noted, however, that applicant has not filed a certified copy of the S990016 application as required by 35 U.S.C. 119(b).

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: ABDOMINAL BELT WITH ADJUSTABLE

ELECTRODES.

Claim Objections

3. Claim 35 is objected to because of the following informalities: in line 2, "extends" should be changed to --extending--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15-17, 19-20, 27, 33-36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 15 recites the limitation "the rest of the attachment means" in lines 3-4.

Claim 16 recites the limitation "each main locating means" in lines 3-4, while claim 1 refers to "a main locating means".

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Claim 19 recites the limitation "the corresponding set of secondary locating means" in lines 2-3.

Claim 20 recites the limitation "the corresponding set of secondary locating means" in line 2.

Claim 27 recites the limitation "each central electrode" in line 1.

Claim 33 recites the limitation "each main contact means" in lines 2-3

Claim 34 recites the limitation "each electrical connecting means" in line 1, while claim 33 refers to "a main electrical connecting means".

Claim 35 recites the limitation "each secondary contact means" in lines 2-3.

Claim 36 recites the limitation "each electrical connecting means" in line 1, while claim 35 refers to "a secondary electrical connecting means".

There is insufficient antecedent basis for these limitations in these claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 8-11, 14-15, 21-26, 30-31, 38-39, 52-55, 59 and 61-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Linder (5,190,036).

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Regarding claim 1, Linder shows attachment means (14) for extending around the torso of a subject; a main locating means (triangular reference 26) for locating a central electrode (the central electrode of the three electrodes on the right or the central electrode of the three electrodes on the left) adjacent the umbilicus of the subject; and two secondary locating means (semi-circular references 26 on either side of triangular reference 26) provided on the attachment means disposed on opposite sides of the main locating means for locating two corresponding side electrodes (any of the top or bottom electrodes (18) of the three electrodes on the right or left) spaced apart from the central electrode (18) (Fig. 1).

With respect to claim 2, Linder shows the two corresponding electrodes are spaced apart from the central electrode in a general direction towards a corresponding *one* of the left or right mid axillary line of the torso intermediate the rib cage and the corresponding right and left iliac crests. The examiner points out that the central electrode could be interpreted to be the middle electrode of the three electrodes (18) located on the left side of the belt, and the two corresponding electrodes could be any of the three electrodes (18) located on the right side of the belt in a general direction towards a corresponding right mid axillary line of the torso intermediate the rib cage and the corresponding right iliac crest.

Regarding claims 3-5, Linder shows the secondary locating means (semi-circular references 26 on either side of triangular reference 26) are disposed on the attachment means for locating the respective side electrodes adjacent the corresponding mid-axillary line or adjacent or toward the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest (Fig. 1).

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Regarding claims 8-10, Linder shows the a reference means (26) for locating the attachment means on the torso relative an anatomic reference, circumferentially around the torso and vertically along the torso (Fig. 1).

With respect to claim 11, Linder shows the main locating means (triangular reference 26) acts as a reference means for locating the attachment means relative to the umbilicus (Fig. 1).

Regarding claims 14-15, Linder further shows the attachment means is formed of resilient material (Col. 2, lines 66-67).

With respect to claims 21-22, Linder further shows each main and secondary locating means (26) is provided as a visually perceptible locating means and formed as a corresponding locating mark on the attachment means (Fig. 1).

Regarding claims 23-25, Linder shows each locating means is adapted for locating a patch type electrode and the at least three electrodes are formed as a removable part of the device (Fig. 1; Col. 3, lines 24-28).

With respect to claim 26, Linder shows each side electrode is sized to cover at least a portion of the corresponding lower thoracic nerves and corresponding first and second lumbar nerves (Fig. 1).

Regarding claims 30-31, Linder further shows an electrically conductive gel-type coating provided on a side of each electrode facing away from the attachment means for electrically coupling the electrode to the torso of the subject (Col. 3, lines 24-33).

With respect to claims 38-39, Linder further shows the attachment means comprises a belt (14) and a securing means (Fig. 1; Col. 2, line 67-Col. 3, line 3).

Regarding claim 52, Linder shows a method comprising providing at least three electrodes (18), one of the at least three electrode being a central electrode located adjacent the

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umbilicus of the subject, and the other two electrodes are side electrodes spaced apart on the subject from the central electrode and located on the subject on respective sides of the central electrode in a general direction towards *one* of the left and right mid axillary lines intermediate the rib cage and corresponding left and right iliac crests and passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes. Again, the examiner points out that the central electrode could be interpreted to be the middle electrode (18) of the three electrodes (18) located on the left side of the belt, and the two corresponding electrodes could be any of the three electrodes (18) located on the right side of the belt in a general direction towards a corresponding right mid axillary line of the torso intermediate the rib cage and the corresponding right iliac crest.

With respect to claims 53-55, Linder shows each side electrode (18) is located towards and adjacent the midpoint of the corresponding mid axillary line of the torso intermediate the rib cage and the corresponding iliac crest (Fig. 1).

Regarding claim 59, Linder further shows the step of applying the at least one pulse signal to the subject.

With respect to claims 61-63, Linder shows a plurality of pulses at intervals in the range of 5 milliseconds to 1000 milliseconds and in the range of 20 milliseconds to 40 milliseconds and approximately 30 milliseconds \pm 20% (Col. 3, lines 51-52). 40Hz roughly corresponds to an interval of 25 milliseconds and 70Hz roughly corresponds to an interval of 14 milliseconds.

Regarding claim 64, Linder shows the interval between pulses is adjustable (Col. 3, lines 38-41, 54-61).

With respect to claims 65-68, Linder shows each pulse signal comprises pulses of duration in the range of 50 microseconds to 2000000 microseconds, pulses of duration in the

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range of 50 microseconds to 1000 microseconds, pulses of duration in the range of 100 microseconds to 500 microseconds, pulses of duration of approximately 300 microseconds \pm 20% (Col. 3, lines 46-50).

Regarding claim 69, Linder shows the duration of each pulsed is adjustable (Col. 3, lines 38-41, 46-50).

With respect to claim 70, Linder shows each pulsed signal comprises a plurality of pulses of magnitude in the range of 0mA to 100mA (Col. 3, lines 65-68).

Regarding claim 71, Linder shows the magnitude of each pulse of each pulsed signal is adjustable (Col. 3, lines 38-41, 62-68).

9. Claims 1-12, 14-23, 27-28, 32-36, 38-39, 52-60, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Hurtado (6,341,237).

Regarding claim 1, Hurtado shows a device including attachment means (120) for extending around the torso of a subject; a main locating means (track 36) for locating a central electrode (144) adjacent the umbilicus of the subject; and two secondary locating means (tracks 36) provided on the attachment means disposed on opposite sides of the main locating means for locating two corresponding side electrodes (146, 148, 150, 152) of the at least three electrodes spaced apart from the central electrode (144) (Fig 9; Col. 10, line 40-Col. 11, line 17; Figs. 3 6; Col 9, lines 51-58).

With respect to claim 2, Hurtado shows the two corresponding electrodes (146, 148, 150, 152) are spaced apart from the central electrode (144) in a general direction towards a corresponding one of the left or right mid axillary line of the torso intermediate the rib cage and the corresponding right and left iliac crests (Fig 9; Col. 10, line 40-Col. 11, line 17).

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Regarding claims 3-5, Hurtado shows the secondary locating means (tracks 36) are disposed on the attachment means for locating the respective side electrodes toward the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest, adjacent the corresponding mid-axillary line, and adjacent the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest (Fig 9; Col. 10, line 40-Col. 11, line 17; Figs. 3 6; Col 9, lines 51-58).

With respect to claims 6-7, Hurtado shows the main locating means (track 36) is disposed on the attachment means for locating the central electrode on the umbilicus and extending completely around the umbilicus (Figs. 7-9, Col. 4, line 65-Col. 5, line 21; Col. 10, lines 53-60).

Regarding claims 8-10, Hurtado shows the a reference means (tracks 36) for locating the attachment means on the torso relative an anatomic reference, circumfrentially around the torso and vertically along the torso (Figs. 3, 6-9).

With respect to claim 11, Hurtado shows the main locating means (track 36 for electrode 144) acts as a reference means for locating the attachment means relative to the umbilicus (Figs. 3, 6-9; Col. 4, line 65-Col. 5, line 21; Col. 10, lines 53-60).

Regarding claim 12, Hurtado shows at least two sets (tracks 36 of electrodes 150 and 152, and tracks 36 for electrodes 146, and 148) of at least two secondary locating means disposed on the opposite sides of the main locating means (Figs. 3, 6, 9).

With respect to claims 14-15, Hurtado further shows the attachment means is formed of resilient material (Col. 10, line 45-47; Col. 9, lines 3-20).

Regarding claims 16-18, Hurtado further shows the main electrically conductive contact means (36) is provided on the attachment means corresponding to the main locating means and located within and adjacent to the main locating means (36) (Col. 9, lines 54-55).

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Regarding claims 19-20, Hurtado further shows each secondary contact means (tracks 36) is located adjacent the secondary locating means or the corresponding set of secondary locating means (Figs. 3, 6, 9).

With respect to claims 21-22, Hurtado further shows each main and secondary locating means (tracks 36) is provided as a visually perceptible locating means and formed as a corresponding locating mark on the attachment means (Figs. 3, 6).

Regarding claim 23, Hurtado shows each locating means (36 is adapted for locating a patch type electrode (Figs. 2, 3, 6).

With respect to claim 27, Hurtado shows each central electrode (140, 142, 144) is sized to extend substantially across the rectus abdominus muscle (Fig. 9; Col. 10, line 40-Col. 11, line 17).

Regarding claim 28, Hurtado further shows the area of contact of each side electrode (146, 148, 150, 152) does not exceed the area of contact of the central electrode (144) (Fig. 9).

With respect to claim 32, Hurtado further shows a receiving means provided in the attachment means for receiving a signal generating means (121) (Col. 11, lines 19-20).

Regarding claims 33-36, Hurtado further shows main and secondary electrical connecting means (dashed lines) extending between the receiving means and the signal generating means (121) and the main contact means (Figs. 1-3, 6, 9).

With respect to claim 38-39, Hurtado further shows the attachment means comprises a belt (124) and a securing means (130) (Fig. 9).

Regarding claim 52, Hurtado shows a method comprising providing at least three electrodes (140, 142, 144, 146, 148, 150, 152), one of the at least three electrodes being a central electrode (140, 142, 144) located adjacent the umbilicus of the subject, and the other two

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electrodes are side electrodes spaced apart on the subject from the central electrode and located on the subject on respective sides of the central electrode in a general direction towards one of the left and right mid axillary lines intermediate the rib cage and corresponding left and right iliac crests and passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes (Fig. 9; Col. 4, line 48-Col. 5, line 21; Col. 10, line 40-Col. 11, line 33).

With respect to claims 53-55, Hurtado shows each side electrode (146, 148, 150, 152) is located towards and adjacent the midpoint of the corresponding mid axillary line of the torso intermediate the rib cage and the corresponding iliac crest (Fig 9; Col. 10, line 40-Col. 11, line 17).

With respect to claims 56-57, Hurtado shows the central electrode (140, 142, 144) is located on the umbilicus and extends completely around the umbilicus (Figs. 7-9, Col. 4, line 65-Col. 5, line 21; Col. 10, lines 53-60).

Regarding claim 58, Hurtado shows the central electrode (140, 142, 144) is located on the umbilicus but with a greater area of the central electrode (142, 144) located below the umbilicus than above the umbilicus (144, 140) (Fig. 9; Col. 10, line 40-Col. 11, line 33).

With respect to claim 59, Hurtado further shows the step of applying the at least one pulse signal to the subject.

Regarding claim 60, Hurtado further shows the at least one pulsed signal is applied simultaneously to each of the side electrodes (Col. 11, lines 27-33).

Regarding claim 71, Hurtado further shows the magnitude of each pulse of each pulsed signal is adjustable (Col. 3, lines 63-67).

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Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) as applied to claim 12. Hurtado discloses the claimed invention except for each set of secondary locating means comprising three secondary locating means. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify each set of secondary locating means with two secondary locating means as taught by Hurtado with each set of secondary locating means having three secondary locating means, since applicant has not disclosed that this third locating means provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any number of secondary locating means in the set of secondary locating means such as the two secondary locating means as taught by Hurtado for locating electrodes on the belt.

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linder (5,190,036). Linder discloses the claimed invention except for the specific size of the each side electrode. It would have been an obvious matter of design choice to form the side electrode having a width of 50 mm to 150 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

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13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237). Hurtado discloses the claimed invention except for the specific size of the each side electrode. It would have been an obvious matter of design choice to form the side electrode having a width of 50 mm to 150 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

14. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) as applied to claim 32 above, and further in view of Russek (4,381,012). Although Hurtado fails to show the receiving means is a releasable receiving means for releasably

receiving the signal generating means, attention is directed to Russek which shows a similar device and teaches that the attachment means comprises receiving means made of VELCRO for releasably receiving the signal generating means. Russek teaches that the releasable receiving means allows for the signal generating means to be located in a convenient location on the attachment means (Col. 6, lines 43-53). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hurtado with receiving means made of VELCRO for releasably receiving the signal generating means in order to allow for the signal generating means to be located in a convenient location on the attachment means.

15. Claims 40-45, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) as applied to claim 1 above, and further in view of Russek (4,381,012). Although Hurtado fails to show a main fastening means provided corresponding to the main locating means and secondary fastening for fastening the respective side electrodes to the attachment means adjacent the secondary located means, attention is directed to Russek which

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shows a similar device with fastening means comprising stud fasteners (Figs. 9-11, 18; Col. 5, lines 26-54). Russek teaches that utilizing stud fastener fastening means is advantageous since it allows wires to be run external to the belt rather than within the belt resulting in a minimal number of wires that can be damaged during laundering (Col. 5, lines 47-54). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hurtado with a main fastening means and secondary fastening means comprising stud fasteners since Russek teaches stud fastener fastening means are advantageous since it allows wires to be run external to the belt rather than within the belt resulting in a minimal number of wires that can be damaged during laundering.

Regarding claim 44, Russek further shows each stud fastener comprises a female (61-66) and male part (66') (Figs. 9-10, 18)

With respect to claim 45, Russek further shows each stud fastener is electrically conductive (Col. 5, lines 26-54).

Regarding claims 48-49, Russek shows each stud fastener comprises a first part (57) for attaching to a corresponding electrode and a second part (66) for attaching to the attachment means wherein the first and second parts engage each other with electrically conductive engagement.

16. Claims 46-47, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) and Russek (4,381,012) as applied to claims 44 and 48 above. Hurtado and Russek disclose the claimed invention except for showing the exposed surface of the portions of each stud fastener attached to the attachment means is of electrically insulating material provided by an electrically insulated coating. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the exposed portions of the

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stud fasteners as taught by Hurtado and Russek with insulating coatings in order to protect a user who may come into contact with the exposed portions of the stud fasteners from electrical shock.

Conclusion

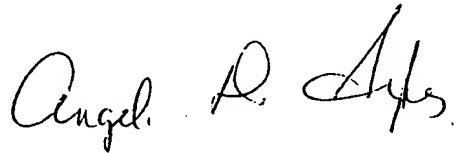
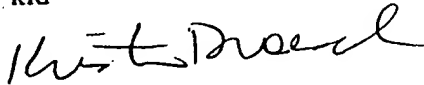
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

kld



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

EXHIBIT D

PATENT
660057-2005IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Michael Conor MINOGUE
Michael Louis CROWE

U.S. Appln. No. : 09/902,287

U.S. Filing Date : July 10, 2001

Title of Invention : AN ELECTROTHERAPY DEVICE AND
METHOD

Examiner: K. Droesch

Group Art Unit: : 3762

11/A
B. Webb
3/17/04

745 Fifth Avenue
New York, NY 10151

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I hereby certify that this correspondence is being deposited with
the United States Postal Service as first class mail in an envelope
addressed to: Commissioner for Patents, P.O. Box 1450,
Alexandria, VA 22313-1450, on March 9, 2004.

Nathan Weber Reg No 50,958
Name of Applicant, Assignee or Registered Representative

[Signature]
Signature

March 9, 2004
Date of Signature

RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

This Response is submitted in response to the Office Action of September 12, 2003.

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Please amend the above-referenced application as follows:

IN THE SPECIFICATION

1. Please rewrite the title of the present invention as suggested by the Examiner as follows:

--ABDOMINAL BELT WITH ADJUSTABLE ELECTRODES--

2. Immediately following the Title of the Invention on page 1 please insert the following:

-- CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of PCT/IE00/00004, filed on
January 11, 2000 which claims the benefit of priority to Irish Application No.
S1999/0016, filed on January 11, 1999.

Background of the Invention

1. ^{Field} ~~Filed~~ of the Invention--

3. Immediately following the first full paragraph on page 1 (approximately line 8) please insert
the following:

--2. Description of the Prior Art--

4. Immediately following the first full paragraph on page 2 (approximately line 9) please insert
the following:

--Summary of the Invention--

5. Immediately following the last full paragraph on page 16 (approximately line 27) please insert
the following:

--Brief Description of the Figures--

6. Immediately following the description of Fig. 30 on page 19 (approximately line 2) please insert the following:

--Detailed Description of the Preferred Embodiments--

IN THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A device for attaching at least three electrodes to a subject for stimulating abdominal muscles of the subject, comprising:

attachment means for extending around the torso of the subject;

a main locating means provided on the attachment means for locating a central electrode of the at least three electrodes adjacent substantially about the umbilicus of the subject;

and

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two secondary locating means provided on the attachment means disposed on ~~respective opposite sides of the main locating means for locating two corresponding side~~
electrodes of the at least three electrodes ~~spaced apart from the central electrode~~, a first of the two side electrodes spaced apart from the central electrode in a general direction towards the left mid-axillary of the subject and a second of the two side electrodes spaced apart from the central electrode in a general direction towards the right mid-axillary line of the subject;

wherein application of at least one pulsed signal to the subject through the respective central and side electrodes stimulates the abdominal muscles of the subject.

2. (Cancelled)

3. (Original) The device as claimed in claim 1 wherein the secondary locating means are disposed on the attachment means for locating the respective side electrodes towards the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest.

4. (Original) The device as claimed in claim 1 wherein the secondary locating means are disposed on the attachment means for locating the respective side electrodes adjacent the corresponding mid-axillary line.

5. (Original) The device as claimed in claim 4, wherein the secondary locating means are disposed on the attachment means for locating the respective side electrodes adjacent the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest.

Q2 6. (Original) The device as claimed in claim 1, wherein the main locating means is disposed on the attachment means for locating the central electrode on the umbilicus and extending around the umbilicus.

7. (Original) The device as claimed in claim 1, wherein the main locating means is disposed on the attachment means for locating the central electrode on the umbilicus and extending completely around the umbilicus.

8. (Original) The device as claimed claim 1, further comprising a reference means provided on the attachment means for locating the attachment means on the torso relative to an anatomical reference.

9. (Original) The device as claimed in claim 8, wherein the reference means is provided for locating the attachment means circumferentially around the torso.

10. (Original) The device as claimed in claim 8, wherein the reference means is provided for locating the attachment means vertically along the torso.

11. (Original) The device as claimed in claim 8, wherein the main locating means acts as the reference means for locating the attachment means relative to the anatomical reference provided by the umbilicus.

12. (Original) The device as claimed in claim 1, further comprising two sets of at least two secondary locating means disposed on the respective opposite sides of the main locating means for facilitating selective location of the respective side electrodes for accommodating different girths of torso.

13. (Original) The device as claimed in claim 12, wherein each set of secondary locating means comprises three secondary locating means.

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14. (Original) The device as claimed in claim 1, wherein portions of the attachment means on respective opposite sides of the main locating means between the main locating means and the corresponding secondary locating means are formed of resilient material for facilitating resilient stretching of the attachment means between the main and corresponding secondary locating means.

15. (Currently Amended) The device as claimed in claim 14 characterized in that the attachment means comprises ~~is formed of~~ a resilient material for facilitating stretching of the attachment means around the torso, the resilient portions of the attachments means being of greater stretchability than that of ~~the rest of the~~ other materials of the attachment means.

16. (Currently Amended) The device as claimed in claim 1, further comprising a main electrically conductive contact means provided on the attachment means corresponding to ~~each~~ the main locating means for receiving the at least one pulsed signal and for relaying the signal to the corresponding central electrode.

17. (Original) The device as claimed in claim 16, wherein each main contact means is located within the corresponding main locating means.

18. (Original) The device as claimed in claim 1, further comprising two secondary electrically conductive contact means provided on the attachment means for receiving the at least one pulsed signal and for relaying the signal to the respective corresponding side electrodes.

19. (Currently Amended) The device as claimed in claim 18, wherein each secondary contact means is located adjacent the corresponding secondary locating means ~~or the corresponding set of secondary locating means.~~

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20. (Currently Amended) The device as claimed in claim 18, wherein each secondary contact means is located adjacent the ~~corresponding set of~~ secondary locating means so that irrespective of which secondary locating means is selected for locating the corresponding side electrode the side electrode is in electrically conductive engagement with the secondary contact means.

21. (Original) The device as claimed in claim 1, wherein each main and secondary locating means is provided as a visually perceptible locating means.

22. (Original) The device as claimed in claim 1, wherein each main and secondary locating means is formed as a corresponding locating mark on the attachment means.

23. (Original) The device as claimed in claim 1, wherein each locating means is adapted for locating a patch type electrode.

24. (Original) The device as claimed in claim 1, wherein the at least three electrodes are formed as a removable part of the device.

25. (Original) The device as claimed in claim 24, wherein each electrode is a patch type electrode.

26. (Original) The device as claimed in claim 25, wherein each side electrode is sized to cover at least a portion of the corresponding lower thoracic nerves and the corresponding first and second lumbar nerves.

27. (Currently Amended) The device as claimed in claim 25, wherein each the central electrode is sized to extend substantially across the rectus abdominus muscle.

28. (Original) The device as claimed in claims 25, wherein each electrode defines an area of contact over which the electrode makes direct electrical contact with the subject, the area of contact of each side electrode being such as not to exceed the area of contact of the central electrode.

29. ~~(Original) The device as claimed in claim 28, wherein each side electrode is of~~
width in a circumferential direction relative to the torso of the subject in the range of 50 mm to 150 mm.

30. (Original) The device as claimed in claim 25, further comprising an electrically conductive coating provided on a side of each electrode facing away from the attachment means for electrically coupling the electrode to the torso of the subject.

31. (Original) The device as claimed in claim 30, wherein the coating is a gel type coating.

32. (Original) The device as claimed in claim 1, further comprising a receiving means provided in the attachment means for receiving a signal generating means for generating the at least one pulsed signal.

33. (Currently Amended) The device as claimed in claim 32, further comprising a main electrical connecting means extending between the receiving means and signal generating

means, and each a main contact means for relaying the at least one pulsed signal from the signal generating means to the corresponding main contact means.

34. (Currently Amended) The device as claimed in claim 33, wherein each the electrical connecting means is located within the attachment means.

35. (Currently Amended) The device as claimed in claim 32, further comprising a secondary electrical connecting means ~~extends~~ extending between the receiving means and each the secondary contact means for relaying the at least one pulsed signal from the signal generating means to the corresponding secondary contact means.

36. (Currently Amended) The device as claimed in claim 35, wherein each the electrical connecting means is located within the attachment means.

37. (Original) The device as claimed claim 32, wherein the receiving means is a releasable receiving means for releasably receiving the signal generating means.

38. (Original) The device as claimed in claim 1, wherein the attachment means comprises a belt.

39. (Original) The device as claimed in claim 38, further comprising a securing means provided on the belt for securing the belt around the torso of the subject.

40. (Original) The device as claimed in claim 1, further comprising a main fastening means provided corresponding to the main locating means for fastening a central electrode to the attachment means adjacent the corresponding main locating means.

41. (Original) The device as claimed in claim 40, wherein the main fastening means comprises a stud fastener.

42. (Original) The device as claimed in claim 1, further comprising two secondary fastening means provided in the attachment means for fastening the respective side electrodes to the attachment means adjacent the corresponding selected secondary locating means.

43. (Original) The device as claimed in claim 42, wherein each fastening means comprises a stud fastener.

44. (Original) The device as claimed in claim 43, wherein each stud fastener comprises a female part and a male part.

45. (Original) The device as claimed in claim 44, wherein each stud fastener is electrically conductive so that the portions of the stud fasteners fastened to the attachment means form the corresponding contact means.

46. (Original) The device as claimed in claim 44, wherein an exposed surface of the portions of each stud fastener fastened to the attachment means is of electrically insulating material.

47. (Original) The device as claimed in claim 46, wherein the exposed surface of each part of each stud fastener attached to the attachment means is coated with an electrically insulating coating.

48. (Original) The device as claimed in claim 43, wherein the stud fastener comprises a first part for attaching to a corresponding electrode, and a second part for attaching to the attachment means.

49. (Original) The device as claimed in claim 48, wherein the first and second parts of the stud fastener engage each other with electrically conductive engagement.

50. (Original) The device as claimed in claim 48, wherein an exposed external surface of the second part of the stud fastener which abuts the first part of the stud fastener is of electrically insulating material.

51. (Original) The device as claimed in claim 50, wherein the electrically insulating material is provided by an electrically insulated coating on the exposed abutting surface.

52. (Currently Amended) A method for stimulating abdominal muscles of a subject, comprising the steps of:

Q2 providing at least three electrodes, one of the at least three electrodes being a central electrode located adjacent substantially about the umbilicus of the subject, and the other two electrodes being side electrodes located on the subject spaced apart from the central electrode, a first of the side electrodes being located substantially about the left mid-axillary line and a second of the side electrodes being located substantially about the right mid-axillary line ~~on respective sides thereof in a general direction towards a corresponding one of the left and right mid-axillary lines of the torso intermediate the rib cage and corresponding left and right~~ iliac crests; and

passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes.

53. (Original) The method as claimed in claim 52, wherein each side electrode is located towards the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest.

54. (Original) The method as claimed in claim 52, wherein each side electrode is located adjacent the corresponding mid-axillary line.

55. (Original) The method as claimed in claim 54, wherein each side electrode is located adjacent the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest.

56. (Original) The method as claimed in claim 52, wherein the central electrode is located on the umbilicus and extends around the umbilicus.

57. (Original) The method as claimed in claim 52, wherein the central electrode is located on the umbilicus and extends completely around the umbilicus.

58. (Original) The method as claimed in claim 52, wherein the central electrode is located on the umbilicus, but with a greater area of the central electrode located below the umbilicus than above the umbilicus.

59. (Original) The method of claim 52, further comprising the step of applying the at least one pulsed signal to the subject so that the signal passes subcutaneously through the subject between the at least three electrodes.

60. (Original) The method as claimed in claim 52, wherein the at least one pulsed signal is applied simultaneously to each of the side electrodes.

61. (Original) The method as claimed in claim 52, wherein each pulsed signal comprises a plurality of pulses at intervals in the range of 5 milliseconds to 1000 milliseconds.

62. (Original) The method as claimed in claim 61, wherein each pulsed signal comprises a plurality of pulses at intervals in the range of 20 milliseconds to 40 milliseconds.

63. (Original) The method as claimed in claim 62, wherein each pulsed signal comprises a plurality of pulses at intervals of approximately 30 milliseconds \pm 20%.

64. (Original) The method as claimed claim 52, wherein the interval between pulses of each pulsed signal is adjustable.

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65. (Original) The method as claimed in claim 52, wherein each pulsed signal comprises pulses of duration in the range of 10 microseconds to 200000 microseconds.

66. (Original) The method as claimed in claim 65, wherein each pulsed signal comprises pulses of duration in the range of 50 microseconds to 1000 microseconds.

67. (Original) The method as claimed in claim 66, wherein each pulsed signal comprises pulses of duration in the range of 100 microseconds to 500 microseconds.

68. (Original) The method as claimed in claim 67, wherein each pulsed signal comprises pulses of duration of approximately 300 microseconds \pm 20%.

69. (Original) The method as claimed in claim 52, wherein the duration of each pulsed signal is adjustable.

70. (Original) The method as claimed in claim 52, wherein each pulsed signal comprises a plurality of pulses of magnitude in the range of 0 mA to 100 mA.

71. (Original) The method as claimed in claim 52, wherein the magnitude of each pulse of each pulsed signal is adjustable.

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, and 3-71 are pending with all claims having been rejected by the Office Action. Claim 2 has been cancelled by these amendments.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112, but rather the amendments and remarks made herein are simply for clarification and to round out the scope of protection to which Applicants are entitled.

The amendments to the specification have been made to place the application in conformity with U.S. customary practice and 37 C.F.R. 1.77.

The Examiner has indicated that to perfect priority based upon an application filed in Ireland on 1/11/1999 a certified copy of the application must be filed with the U.S. Patent and Trademark Office. In an effort establish the claim of priority, a certified copy of the Irish Application has been ordered and will be submitted in a supplemental response to this Office Action. In any event an un-certified copy of the priority document is submitted herewith in order to further prosecution.

The title of the application has been objected to, in response, the title suggested by the Examiner has been substituted for the original title to overcome this objection. Accordingly, it is requested that this objection be withdrawn.

Finally, the Examiner has objected to claim 35 due to an informality. In response, claim 35 has been amended as suggested by the Examiner and it is requested that the objection be withdrawn.

II. 35 U.S.C. § 112

Claims 15-17, 19-20, 27, and 33-36 have been rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Office Action points out instances of insufficient antecedent basis. In response, the claims listed above have been amended to correct these insufficiencies. Accordingly, it is respectfully requested that the rejections under § 112, second paragraph be withdrawn.

III. 35 U.S.C. § 102 REJECTIONS

The Office Action rejects claims 1-5, 8-11, 14-15, 21-26, 30-31, 38-39, 52-55, 59, and 61-71 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,190,036 to Linder. To the best of Applicants attorney's understanding, the Office Action argues that the location of the central and side electrodes is taught by Linder in that the center electrode of the two sets of three electrodes is adjacent the umbilicus and the other two electrodes are adjacent the respective left and right mid-axillary lines of the subject.

In response, claims 1 and 52 have been amended to clarify that the central electrode is located "substantially about" the umbilicus of the subject and that the side electrodes are located "substantially about" the respective left and right mid-axillary lines. In other words, there is one electrode in the region of the left mid-axillary line, one in the region of the right mid-axillary line, and one in the region of the umbilicus. Linder does not teach such a configuration of electrodes. Accordingly, it is respectfully submitted that independent claims 1 and 52 as

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amended patentably distinguish over Linder and are allowable. Claims 3-51, and 53-71 depend from allowable base claims and are allowable therewith.

The Office Action also rejects claims 1-12, 14-23, 27-28, 32-36, 38-39, 52-60, and 71 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,341,237 to Hurtado. As discussed above it is respectfully submitted that this application is a continuation application of PCT/IE00/00004, filed on January 11, 2000 which claims the benefit of priority to Irish Application No. S1999/0016, filed on January 11, 1999. Further, it is submitted that a certified copy of the priority document has been ordered and shall be submitted in a supplemental response. Accordingly, as the present invention claims priority to a date which predates the earliest priority date of Hurtado, it is respectfully requested that these rejections be withdrawn.

Finally, the Office Action rejects claims 13, 29, 37, 40-51 as unpatentable over combinations of Hurtado, Linder, and U.S. Patent No. 4,381,012 to Russek. As both Linder and Hurtado have been distinguished above, and because these rejections deal solely with dependent claims that depend from an allowable base claim, it is respectfully submitted that these claims patentably distinguish over the combinations of references are allowable.

Accordingly, withdrawal of the rejections and allowance of claims 1, and 3-71 is respectfully requested.

CONCLUSION

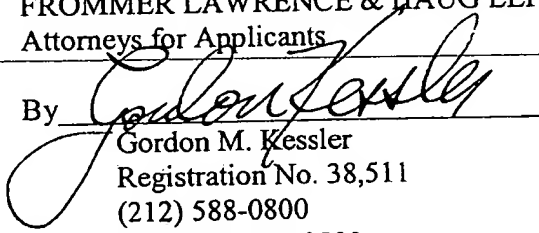
In view of the foregoing amendments and remarks, it is believed that all of the claims in this application are patentable over the prior art, and early and favorable consideration thereof is solicited.

Please charge any fees incurred by reason of this response and not paid herewith to Deposit Account No. 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By


Gordon M. Kessler
Registration No. 38,511
(212) 588-0800
Fax (212) 588-0500

3762\$

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant(s)

Michael Conor MINOGUE
Michael Louis CROWE

U.S. Appln. No. : 09/902,287

U.S. Filing Date : July 10, 2001

Title of Invention: AN ELECTROTHERAPY DEVICE AND METHOD

Examiner: K. Droesch

Group Art Unit : 3762

745 Fifth Avenue
New York, NY 10151
Tel: 212-588-0800RECEIVED
MAR 16 2004
TECHNOLOGY CENTER R3700Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is an amendment in the above-identified application.

- ☐ No additional fee is required.
- ☒ The fee has been calculated as shown below.
- ☒ This is an application of a small entity under 37 CFR 1.9(f), and the amounts shown in parentheses apply.

Claims as Amended

(1)	(2) Claims remaining after amendment	(3)	(4) Highest number previously paid for	(5) Present extra	(6) Rate	(7) Additional Fee
Total claims	68	Minus	** = 69	* 0 x	\$18 (9)	= \$ 0
Independent claims	2	Minus	*** = 3	* 0 x	\$86 (43)	= \$ 0
Total additional fee for this amendment						\$ 0

- * If the entry in Column 2 is less than the entry in Column 4, write "0" in Column 5.
- ** If the highest number of total claims previously paid for is less than 20, write "20" in this space.
- *** If the highest number of independent claims previously paid for is less than 3, write "3" in this space.

- ☐ This application contains a multiple dependent claim. The required fee of \$290(145) has been previously paid ☐, or is paid herewith ☐.
- ☒ This response is being filed within the third (3rd) month following the expiration of the term originally set therefor. This is a petition to request a three (3) month extension of time. A check covering the cost of the petition is enclosed.
- ☒ A check in the amount of \$475.00 is attached, which covers the cost of ☐ additional claims _____ petition for extension of time.
- ☐ Charge \$ _____ to Deposit Account No. 50-0320.
- ☒ Please charge any additional fees incurred by reason of this response or credit any overpayment to Deposit Account No. 50-0320.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 9, 2004.

Name of Applicant, Assignee or Registered Representative

Signature

March 9, 2004

Date of Signature

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By:

Gordon M. Kessler
Reg. No. 38,511
Tel: 212-588-0800

REQUEST FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. §1.136, a three-month extension of the period for reply, i.e., up to and including March 12, 2004, is respectfully requested. A check for \$475.00 in payment of the fee under 37 C.F.R. §1.17(a) is enclosed. The Commissioner is authorized to charge any additional fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

EXHIBIT E



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov



Bib Data Sheet

CONFIRMATION NO. 8694

SERIAL NUMBER 09/902,287	FILING DATE 07/10/2001 RULE	CLASS 607	GROUP ART UNIT 3766	ATTORNEY DOCKET NO.
-----------------------------	---------------------------------------	--------------	------------------------	------------------------

APPLICANTS

Michael Conor Minogue, Croshua, IRELAND;

Michael Louis Crowe, Dublin, IRELAND;

verified KDM

** CONTINUING DATA *****

none KDM

** FOREIGN APPLICATIONS *****

IRELAND S990016 01/11/1999

*verified KDM*IF REQUIRED, FOREIGN FILING LICENSE GRANTED
** 08/28/2001

** SMALL ENTITY **

Foreign Priority claimed <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	STATE OR COUNTRY IRELAND	SHEETS DRAWING 10	TOTAL CLAIMS 71	INDEPENDENT CLAIMS 2
35 USC 119 (a-d) conditions met <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	Verified and Acknowledged Examiner's Signature <i>[Signature]</i> Initials <i>KDM</i>			

ADDRESS

20999
 FROMMER LAWRENCE & HAUG
 745 FIFTH AVENUE- 10TH FL.
 NEW YORK, NY
 10151

TITLE

*See SPEC 3/11/04**Electrotherapy device and method Abdominal Belt with Adjustable Electrodes*

FILING FEE RECEIVED 969	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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EXHIBIT F

Please type a plus sign (+) inside this box → [X]

PTO/SB/05 (09/04)

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

051206

17567 U.S. PTO

**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.

660057-2005.1

First Inventor

Michael Conor Minogue et al.

Title

AN ELECTROTHERAPY DEVICE AND METHOD

Express Mail Label No.

EV746685473US

112959 U.S. PTO
11/484436

051206

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

Addressed to: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1. ☒ **Fee Transmittal Form (e.g., PTO/SB/17)**
(Submit an original, and a duplicate for fee processing)
2. ☒ **Applicant claims small entity status.**
See 37 CFR 1.27.
3. ☒ **Specification, including Abstract** [Total Pages 43]
Both the claims and abstract must start on a new page
(For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ **Drawing(s)** (35 U.S.C. 113) [Total Sheets 10]
5. **Oath or Declaration** [Total Pages 2]
 - a. ☐ Newly executed (original or copy)
 - b. ☒ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
 - i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s)
named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

6. ☐ **Application Data Sheet.** See 37 CFR 1.76.
7. ☐ **CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)**
8. **Nucleotide and/or Amino Acid Sequence Submission**
(if applicable, all necessary)
 - a. ☐ Computer Readable Form (CFR)
 - b. **Specification sequence Listing on:**
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers (cover sheet & documents(s))**
Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** ☐ **Power of Attorney**
(when there is an assignee)
11. ☐ **English Translation Document (if applicable)**
12. ☒ **Information Disclosure Statement (PTO/SB/08 or PTO-1449)**
☐ Copies of citations attached
13. ☒ **Preliminary Amendment**
14. ☒ **Return Receipt Postcard (MPEP 503)**
(Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
(if foreign priority is claimed)
16. ☐ **Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i).**
Applicant must attach from PTO/SB/35 or its equivalent.
17. ☐ **Other:** _____

18. If a **CONTINUING APPLICATION**, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an **Application Data Sheet** under 37 CFR 1.76:

☐ Continuation ☒ Divisional ☐ Continuation-in-part (CIP)

of prior application No.: 09/902,287

Examiner: Kristen D. Mullen

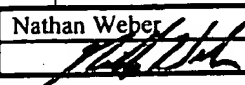
Group/Art Unit: 3766

For **CONTINUATION OR DIVISIONAL APPS** only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS☒ Customer Number

20999

or ☐ Correspondence address below

Name	FROMMER LAWRENCE & HAUG LLP				
Address	745 FIFTH AVENUE				
City	NEW YORK	State	NY	Zip Code	10151
Country	U.S.A.	Telephone	(212) 588-0800	Fax	(212) 588-0500
Name (Print/Type)	Nathan Weber		Registration No. (Attorney/Agent)	50,958	
Signature			Date	May 12, 2006	

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) and application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.1 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the complete application to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

00370885

CERTIFICATE OF MAILING - SEPARATE PAPER

"Express Mail" mailing label number: EV746685473US

Date of Deposit: May 12, 2006

I hereby certify that this Patent Application and the accompanying papers are
being deposited with the United States Postal Service "Express Mail Post Office to Addressee"
service under 37 C.F.R. 1.10 on the date indicated above and is addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Adam Ahmed

(Typed or printed name of person mailing paper or fee)

A. Ahmed

(Signature of person mailing paper or fee)

Effective on 12/08/2004

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

Complete if Known

Application Number	To Be Assigned
Filing Date	Herewith
First Named Inventor	Michael Conor Minogue et al.
Examiner Name	Kristen D. Mullen (Parent Application)
Art Unit	3766 (Parent Application)
Attorney Docket No.	660057-2005.1

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT \$500.00

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☒ Deposit Account Deposit Account Number: 50-0320 Deposit Account Name: Frommer Lawrence & Haug LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s)☐ Credit and overpayments

WARNING: Information on this form may become public. Credit Card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid(\$)
	Fee(\$)	Small Entity Fees(\$)	Fee(\$)	Small Entity Fees(\$)	Fee(\$)	Small Entity Fees(\$)	
Utility	300	150	500	250	200	100	\$500.00
Design	200	100	100	50	130	65	—
Plant	200	100	300	150	160	80	—
Reissue	300	150	500	250	600	300	—
Provisional	200	100	0	0	0	0	—

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent

Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent

Multiple dependent claims

Fee(\$)	Small Entity Fees(\$)
50	25
200	100
360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims
20	-20 or HP = 0 x	50.00 =	0.00	Fee (\$)
HP = highest number of total claims paid for, if greater than 20				
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Fee Paid (\$)
1	-3 or HP = 0 x	200.00 =	0.00	
HP = highest number of total claims paid for, if greater than 3				

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 or small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
53 - 100 =	0/ 50 =	0 (round up to a whole number) x	0.00 =	0.00

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity)

Other: _____

SUBMITTED BY

Signature

Registration No.
(Attorney/Agent)

50,958

Telephone 212-588-0800

Name (Print/Type)

Nathan Weber

Date May 12, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1540. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

EXHIBIT G



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
11/434,436	05/12/2006	3766	500	660057-2005.1	10	20	1

CONFIRMATION NO. 3949

20999
 FROMMER LAWRENCE & HAUG
 745 FIFTH AVENUE- 10TH FL.
 NEW YORK, NY 10151

FILING RECEIPT



OC000000019192823

DOCKETED

Date Mailed: 06/09/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Michael Conor Minogue, Kinvara, IRELAND;
 Michael Louis Crowe, Dublin, IRELAND;

Power of Attorney:

Gordon Kessler-38511

Domestic Priority data as claimed by applicant

This application is a DIV of 09/902,287 07/10/2001 PAT 7,069,089

Foreign Applications

IRELAND S990016 01/11/1999

IRELAND PCT/IE00/00004 01/11/2000

If Required, Foreign Filing License Granted: 06/08/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US11/434,436**

Projected Publication Date: 09/14/2006

Non-Publication Request: No

Early Publication Request: No

2006 JUN 12 A 9:43
 FROMMER, LAWRENCE
 & HAUG, LLP

**** SMALL ENTITY ******Title**

Electrotherapy device and method

Preliminary Class

607

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from ~~specific foreign countries to ensure that patent rights are not lost prematurely.~~

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER**Title 35, United States Code, Section 184****Title 37, Code of Federal Regulations, 5.11 & 5.15****GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

EXHIBIT H



Patents Office
Government Buildings
Hebron Road
Kilkenny

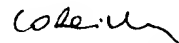
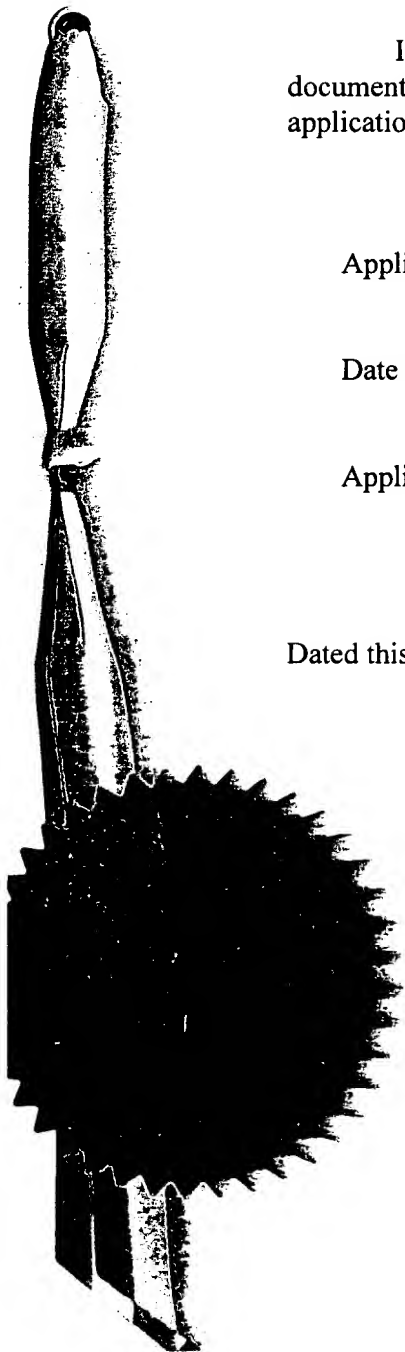
I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No. S1999/0016

Date of Filing 11 January 1999

Applicant BMR RESEARCH & DEVELOPMENT LTD, An Irish company of Bunbeg, County Donegal, Ireland.

Dated this 22 day of February 2010.



An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

S 990016

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)Name

BMR RESEARCH & DEVELOPMENT LTD

Address

Bunbeg, County Donegal, Ireland.

Description/Nationality

An Irish company

2. Title of Invention

"Electrotherapy"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)Previous filing dateCountry in or for
which filedFiling No.4. Identification of Inventor(s)Name(s) of person(s) believed
by Applicant(s) to be the inventor(s)

MICHAEL CONOR MINOGUE and LOUIS MICHAEL CROWE

AddressCroshua, Kinvara, County Galway, Ireland and 65 Beech Park Road, Dublin 18,
Ireland, all Irish citizens.

5. Statement of right to be granted a patent (Section 17 (2) (b))

The applicant has derived the right to be granted a Patent from the inventor(s) by virtue of a Deed of Assignment dated January 8, 1999

6. Items accompanying this Request - tick as appropriate

- (i) ☒ Prescribed filing fee (£ 50.00)
- (ii) ☐ Specification containing a description and claims
- ☒ Specification containing a description only
- ☒ Drawings referred to in description or claims
- (iii) ☐ An abstract
- (iv) ☐ Copy of previous application(s) whose priority is claimed
- (v) ☐ Translation of previous application whose priority is claimed
- (vi) ☐ Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No:

Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name

Address

F.F. GORMAN & CO.

54 Merrion Square,
Dublin 2,
Ireland.

9. Address for Service (if different from that at 8)

F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

F.F. GORMAN & CO., Agents for the Applicants

BY: W. Gorman EXECUTIVE

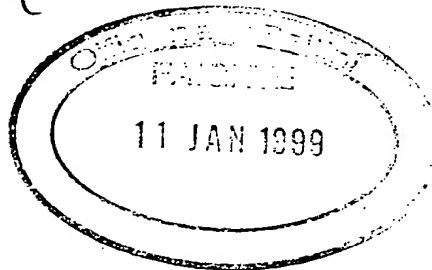
Signed

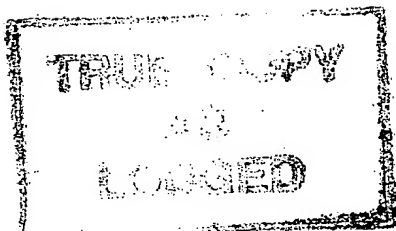
XXXXXXXXXX

Capacity (if applicant is a body corporate):
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Date

January 11, 1999





S 9900 16
APPLICATION No. _____

"Electrotherapy"

This invention relates to electrotherapy and in particular to a method for stimulating nerves and muscles and to an electrode placement device.

5 In electrotherapeutic methods such as transcutaneous electrical nerve stimulation (TENS) and electrical muscle stimulation, electrodes are applied to the skin and electric currents are passed between the electrodes to stimulate nerve and/or muscle tissues
10 under and between the electrodes. Stimulation can provide pain relief and, where muscles are stimulated, improved muscle tone.

In general, electrotherapeutic methods and devices require the use of an electrical generator unit and a
15 source electrode for transmitting current to a tissue and a return electrode for receiving the current from the tissue. Typically, a microprocessor is employed to issue control signals to a plurality of transducer circuits which drive respective electrode pairs made
20 up of the source electrode and the return electrode.

However, a number of disadvantages are associated with the known methods and devices. For example, frequently electrotherapeutic devices are used by persons with a limited knowledge of anatomy which gives rise to

uncertainty and errors in the placement of electrodes. Accordingly, the electrotherapeutic devices are employed in an inefficient manner. Furthermore, where it is necessary to apply several electrodes to the
5 body, considerable time is expended and wasted in applying the electrodes to and removing the electrodes from the skin.

Moreover, in the methods and devices of the prior art, it is normal to employ pairs of electrodes made up of
10 the source electrode and the return electrode. In addition, use of such electrode pairs is generally restricted to electrode pairs disposed parallel with the direction of muscle fibres.

Accurate placement of electrodes in electrotherapeutic
15 devices and methods is also critical to avoid the creation of a transthoracic route for the current as such routes can theoretically cause cardiac arrhythmias. For example, if electrodes are placed in an incorrect position such as over the lower rib cage,
20 transthoracic routes may be generated thereby theoretically enhancing the risk of cardiac arrhythmia. Accordingly, a need exists for a method and device for the easy and accurate placement of electrodes in electrotherapy.

In addition, electrodes in electrotherapy should be placed in order to avoid passage of current for long distances in deep tissues e.g. it may be deemed undesirable for a current to travel near the ovaries.

- 5 In the electrotherapeutic devices and methods of the prior art, a gel or adhesive gel contact is frequently disposed between the electrode and the skin surface in order to maximise contact between the electrode and the skin surface. However, with use, electrical
- 10 contact with the skin is known to deteriorate and an extra layer of adhesive gel must be added or indeed an entire electrode replaced. The necessity of replacing the electrodes or gel adhesive layer clearly gives rise to additional costs and may require complex
- 15 manipulation by a user thereby resulting in reduced or lack of use of electrotherapeutic devices due to the complexity of replacement.

An object of the invention is to overcome the problems of the prior art.

- 20 A further object of the invention is to provide an improved method for stimulating nerves and/or muscles.

A yet further object of the invention is to provide a method for stimulating nerves and/or muscles in which

transthoracic currents are minimised.

A still further object of the invention is to provide an electrode placement device.

A further object of the invention to provide an
5 electrode placement device having electrode protecting means for protecting electrode contacts.

According to the invention there is provided a method for stimulating a nerve comprising locating an electrode on a locus of a body and applying a current
10 to the electrode characterised in that the locus is identified with reference to an anatomical marker. Preferably, the locus is selected to stimulate a muscle. Suitably, the locus is selected from the group comprising a mid-axillary line, an umbilicus, gluteii
15 and a lower back region.

Advantageously, the muscle is selected from the group comprising abdominal muscles, gluteal muscles and dorsal muscles.

Preferably, the electrode is mounted on a belt.
20 Advantageously, the belt is provided with markers for locating the electrodes adjacent the anatomical markers.

Suitably, at least three electrodes are located on the body. Advantageously, the at least three electrodes comprise at least one common return electrode. More preferably, the at least three electrodes comprise two
5 current source electrodes and one common return electrode.

Advantageously, the current paths defined between electrodes are not necessarily parallel to the direction of the muscle fibres.

10 Suitably, the two source electrodes are disposed on respective mid-axillary lines and the return electrode is disposed adjacent the umbilicus. More preferably, at least a portion of the return electrode is located beneath the umbilicus.

15 The invention also extends to a device adapted to perform the method as hereinbefore defined.

The invention also extends to an electrode placement device comprising a belt adapted to locate electrodes on a body with reference to anatomical markers.

20 Suitably, the anatomical markers are selected from the group comprising the umbilicus, the mid-axillary lines, the gluteii and the lower back portion.

Preferably, the electrode placement device further comprises electrodes for applying a current to the body. Advantageously, the electrodes comprise a gel for contacting skin. Suitably, the electrode placing
5 device further comprises reusable release sheets for protecting the electrodes. Preferably, the reusable release sheets are integral with the belt.

The invention also provides an electrode placement device having a switch array for generating a
10 plurality of currents to the electrodes. Various embodiments of the invention will now be described, by way of example only, having regard to the accompanying drawings in which:

Fig. 1 is a schematic front elevation of an
15 abdomen fitted with electrode pairs in accordance with the prior art;

Fig. 2 is a schematic front elevation of an
abdomen having right and left electrodes disposed on respective mid-axillary line adjacent the
20 abdomen;

Fig. 3 is a schematic front elevation of the abdomen of Fig. 2 provided with a central umbilical electrode disposed beneath the

umbilicus;

Fig. 4 is a schematic front elevation of an abdomen provided with right and left electrodes disposed along the mid-axillary lines and a central umbilical electrode, the electrodes being formed into a belt mounted on the abdomen;

Fig. 5 is a schematic front elevation of the belt and electrode arrangement of Fig. 4 in which the central umbilical electrode is arranged in a bottom electrode portion disposed beneath the umbilicus and a top electrode portion disposed above the umbilicus;

Fig. 6 is a schematic side elevation of the torso of Fig. 3 with the right electrode disposed along the mid-axillary line beneath the rib cage and above the iliac crest;

Fig. 7 is a schematic side elevation of the torso of Fig. 2 with the left electrode disposed along the mid axillary line above the iliac crest and beneath the rib cage;

Fig. 8 is a schematic rear elevation of human

gluteii with a left electrode disposed on a left
buttock, a right electrode disposed on a right
buttock and a central lower back electrode
disposed on the lower back between the left and
right buttock electrodes;

Fig. 9 is a schematic rear elevation of the
gluteii of Fig. 8 with the left electrode,
the right electrode and the lower back
electrode formed into a belt;

Fig. 10 is a schematic front elevation of the
abdominal belt of Fig. 4;

Fig. 11 is a schematic front elevation of the
abdominal belt of Fig. 5;

Fig. 12 is a schematic front elevation of an
abdomen provided with a right electrode, left
electrode and central umbilical electrode;

Fig. 13 is a schematic representation of the
electrode array of the belt of Fig. 12 provided
with a single channel stimulus signal generator;

Fig. 14 is a schematic representation of the
currents generated by the electrode array of Fig.

13;

Fig. 15 is a schematic representation of an electrode array similar to the electrode array of Fig. 13 in which the signals from the single channel stimulus signal generator may be balanced;

Fig. 16 is a schematic representation of the current generated by the electrode array of Fig. 15;

Fig. 17 is a schematic representation of an alternative signal generator method employing the electrode array of Fig. 13;

Fig. 18 is a schematic representation of the current generated by the array of Fig. 17;

Fig. 19 is a schematic front elevation of an abdomen provided with the electrodes described in Fig. 5;

Fig. 20 is a schematic representation of a signal generator and the electrode array of Fig. 19;

Fig. 21 is a schematic representation of an

alternative signal generator method employing the electrode array of Fig. 19;

Fig. 22 is a still further arrangement of a signal generator for the electrode array of Fig 19;

Fig. 23 is a schematic representation of the possible current paths generated by the electrode array of Fig. 19;

Fig. 24 is a schematic representation of a signal generator having a pulse sequence generator circuit for the electrode array of Fig. 19;

Fig. 25 is a schematic representation of an array and generator circuit adapted to generate a plurality of current pulses showing the switches employed in the array;

Fig. 26 is a series of schematic front elevations of a portion of a belt in accordance with the invention provided with a releasable sheet for protecting an umbilical electrode made up of a bottom portion and a top portion and Fig. 26b is a series of schematic front elevations of a similar belt having a unitary umbilical

electrode;

5

Fig. 27 is a schematic front elevation of an alternative abdominal belt in accordance with the invention provided with releasable sheets for protecting the electrode;

Fig. 28 is a further embodiment of an abdominal belt provided with the releasable sheets for protecting the electrodes of the belt;

10

Fig. 29 is a further embodiment of an abdominal belt in accordance with the invention provided with fold lines and releasable sheets for protecting the electrodes;

Fig. 30 is a schematic front elevation of the belt of Fig. 29 in a folded disposition;

15

Fig. 31 is a schematic front elevation of an alternative abdominal belt in accordance with the invention;

20

Fig. 32 is a schematic front elevation of a still further embodiment of an abdominal belt in accordance with the invention provided with releasable electrode protecting sheets;

Fig. 33 is a schematic front elevation of the belt of Fig. 32 in a semi-folded disposition;

Fig. 34 is a front elevation of an alternative abdominal belt in accordance with the inventions;

5 Fig. 35 is a front elevation of a still further embodiment of an abdominal belt in accordance with the invention in an unfolded and folded disposition and;

10 Fig. 36 is a front elevation of a further embodiment of an abdominal belt in accordance with the invention in the folded disposition.

Fig. 1 shows a schematic front elevation of a torso 1 of a person 2 between a chest 19 and a pelvis 4. A rib cage 3 is disposed immediately beneath the chest 19. A
15 left iliac crest 6 and a right iliac crest 7 are disposed between the rib cage 3 from the upper portion of the pelvis 4. An abdominal region or abdomen 5 is defined between the left and right iliac crests 6, 7 and the rib cage 3. An umbilicus 8 is visible on the
20 abdomen 5.

The abdomen 5 is provided with an electrotherapeutic

electrode arrangement in accordance with the prior art made up of a first electrode pair 9, a second electrode pair 10, a third electrode pair 11 and a fourth electrode pair 12. Each electrode pair 9, 10, 11, 12 is made up of a source electrode 13 for transmitting current and a return electrode 14 for receiving current from the source electrode. As will be appreciated by those skilled in the art, the first electrode pair, second electrode pair, third electrode pair and fourth electrode pair 9, 10, 11, 12 respectively are in general in communication with a microprocessor and signal generator unit which issues respective control signals to a plurality of transducer circuits which drive the respective electrode pairs 9, 10, 11 and 12.

As shown in Fig. 1, in accordance with the electrotherapeutic method of the prior art, up to eight electrodes are employed on the abdomen 5 to achieve an abdominal muscle toning effect. Typically, four of the electrodes, namely the electrode pairs 9, 10 are located over the rectus abdominis muscle and two electrodes, namely the third and fourth electrode pairs 11, 12, over each of the oblique abdominal muscles.

Accordingly, stimulation of the abdominal muscles in

accordance with the prior art requires the use of one pair of electrodes per target muscle. Therefore, for complex muscle groups, such of those of the abdomen, a plurality of electrodes is required in accordance with

5 the methods of the prior art resulting in:

- a multiplicity of electrodes and associated wires and connectors
- a requirement on a user to correctly locate the electrodes
- 10 - a lengthy set up time and take off time for the electrode pairs 9, 10, 11, 12
- crowding of electrodes on the abdomen 5
- a multiplicity of controls on the microprocessor for the large number of electrode
- 15 pairs employed
- confusion over control of individual electrode pairs 9, 10, 11, 12
- confusion over polarity of electrodes (i.e. location of the source electrode and return
- 20 electrode 13, 14 respectively) and correct placement of the source and return electrodes 13, 14.

Accordingly, in accordance with the method and devices of the prior art, the first second third and fourth

25 electrode pairs 9, 10, 11, 12 respectively are located over a muscle (or closely aligned muscle groups) in

order to stimulate contraction of the muscle. For example as shown in Fig. 1, in the abdomen 5, the rectus abdominis muscle is stimulated by placing electrodes on the overlying skin, above and below the umbilicus 8. Passage of current between the source electrode 13 and return electrode 14 of the first second third and fourth electrode pairs 9, 10, 11, 12 causes excitation of motor nerves innervating the rectus abdominis thereby causing contraction of muscle fibres.

As shown in Fig. 1, the first second third and fourth electrode pairs 9, 10, 11, 12 are typically oriented to be parallel with the direction of the muscle fibres it is desired to stimulate.

Figs. 2 to 7 show various views of the abdomen 5 of Fig. 1 provided with electrodes in accordance with the method of the present invention and also fitted with a device for locating said electrodes in accordance with the present invention.

As shown in the drawings, in accordance with the method of the present invention for stimulating abdominal muscles, a left electrode 15 and a right electrode 16 are mounted on respective left and right mid-axillary lines 17, 18 of the torso 1 of the user

2. The left and right electrodes 15, 16 are located on the respective left and right mid-axillary lines 17, 18 between the rib cage 3 and the respective left and right iliac crests 6, 7.

5 In addition, as shown in the drawings, an umbilical electrode 20 is disposed adjacent the umbilicus 8 between the left and right electrodes 15, 16. The centrally located or umbilical electrode 20 is located substantially beneath the umbilicus 8. The umbilical
10 electrode 20 can serve as a return electrode 14 for the left and right electrodes 15, 16 thereby minimising the number of electrodes required to stimulate the complex abdominal muscle groups.

Surprisingly, the applicants have found that location
15 of the left and right electrodes 15, 16 along the respective left and right mid-axillary lines 17, 18 together with location of the umbilical electrode 20 adjacent the umbilicus 8 results in an optimised electrotherapeutic device and apparatus for abdominal
20 nerve/muscle stimulation. The left and right electrodes 15, 16 may be easily located along the mid-axillary lines 17, 18 which lines serve as anatomical reference markers for optimal location of the left and right electrodes 15, 16. In addition the umbilical
25 electrode 20 may be easily located adjacent and

preferably extending below the umbilicus 8 by reference to the umbilicus 8 which also serves as a constant anatomical reference marker for accurate location of the umbilical electrode 20. Accordingly, the afore-mentioned reference anatomical markers ensure that the electrodes 15, 16, 20 are correctly aligned with target skin and accordingly muscle locations.

Moreover, the applicants have surprisingly found that location of the right and left electrodes 15, 16 along the mid-axillary lines 17, 18 and location of the umbilical electrode 20 adjacent the umbilicus 8 results in efficient and optimised stimulation of the abdominal nerves and muscles without requiring a current path which is broadly co-linear with the direction of the abdominal muscle fibres. Moreover, in accordance with the methods and devices of the present invention, the left and right electrodes 15, 16 and the umbilical electrodes 20 do not require electrode pairs as three electrodes only are required. In addition, stimulation of the rectus abdominis may be efficiently achieved by passing current to and from the umbilical electrode 20 below the umbilicus 8 without the presence of any additional electrode on the rectus abdominis.

Location of the left and right electrodes 15, 16 along the mid-axillary lines 17, 18 ensures effective and optimised stimulation of the transversalis and oblique muscles.

5 The applicants have also found that where the left and right electrodes 15, 16 do not overlap the mid-axillary lines, contraction of the transversalis and oblique muscles dropped precipitously. For example, if the left and right electrodes 15, 16 are placed to the rear of the respective mid-axillary lines 17, 18 contraction of back muscles is stimulated instead of abdominal muscles.

In addition, location of the left and right electrodes 15, 16 ensures maximum stimulation of the lower thoracic nerves and subcostal nerve before the said nerves splay out across the abdomen 5.

In short, location of left and right electrodes 15, 16 along the respective mid-axillary lines 17, 18 and location of the umbilical electrode 20 at the umbilicus 8 facilitates stimulation of abdominal muscles where the umbilical electrode 20 is located over the rectus abdominis.

It should be noted that in the arrangement of the

prior art described in Fig. 1 above, a risk exists that inaccurate placement of the electrode pairs 9, 10, 11, 12 can result in the generation of a transthoracic current path. As indicated previously, such transthoracic current paths can theoretically result in cardiac arrhythmias. Accordingly, in the method and device of the present invention, location of the left and right electrodes 15, 16 on the respective left and right mid-axillary lines 17, 18 and location of the umbilical electrode 20 on the rectus abdominis below the umbilicus 8 ensures that current is passed from the left and right electrodes 15, 16 to the centrally located umbilical electrode 20 so that the generation of a transthoracic current route is prevented. Moreover, the aforementioned arrangement minimises the number of electrodes or electrode pairs in order to achieve abdominal muscle stimulation. In the present embodiment of the invention, the number of electrodes required has been reduced from eight as shown in Fig. 1 to three electrodes shown in Fig. 3.

As shown in Fig. 4 elimination of the risk of transthoracic current path generation and effective and reproducible location of the left and right electrodes 15, 16 and the umbilical electrode 20 is achieved in the present invention by the provision of

a belt 21 on which the left and right electrodes 15, 16 and the umbilical electrode 20 are mounted. The belt 21 is placed on the abdomen 5 by reference to the anatomical mid-axillary line 17, 18 markers and the umbilicus 8 marker.

Fig. 5 shows an alternative arrangement of a belt 21 in accordance with the invention in which the umbilical electrode 20 is sub-divided to form an umbilical electrode bottom portion 22 separated from an umbilical electrode top portion 23. The umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 are spaced apart to rest above and below the umbilicus 8 in use.

The belt 21 is adapted to automatically and correctly locate the left and right electrodes 15, 16 and the umbilical electrode 20 correctly on an abdomen to ensure optimum muscle stimulation. Moreover, use of the centrally located umbilical electrode 20, whilst eliminating transthoracic current paths, also serves to ensure that current between the left and right electrodes 15, 16 and the umbilical electrode 20 does not travel for long distances deep in the tissues thereby eliminating current paths via the ovaries in an easily reproducible and efficient manner.

Figs. 8 and 9 show an alternative arrangement of electrodes in accordance with the present invention for causing nerve and muscle stimulation in the glutei 24. As shown in the drawings, the glutei 24 made up of a left buttock 25 and a right buttock 26 are each provided with a left electrode 27 located on the left buttock 25 and a right electrode 28 located on the right buttock 26. A central lower back electrode 29, similar to the umbilical electrode 20 previously described is located between the left electrode 27 and the right electrode 28 at the lower back intermediate the left buttock 25 and right buttock 26. Accordingly, current paths are defined between the left electrode 27 and the central lower back electrode 29 and the right electrode 28 and the central lower back electrode 29 in a manner similar to the electrodes of the abdomen 5 previously described. Therefore, provision of electrode pairs is not required. Moreover, current may be passed between the left buttock 25 and the right buttock 26 to stimulate the glutei muscles.

As shown in Fig. 9, the left electrode 27, the right electrode 28 and the central lower back electrode 29 are incorporated into a buttock belt 30 for automatic correct positioning of the left electrode 27, right electrode 28 and central lower back electrode 29. In

the present embodiment, the lower back region between the left buttock 25 and right buttock 26 serves as an anatomical marker for correct positioning of the central lower back electrode 29 and hence the left electrode 27 and the right electrode 28. Accordingly, the left electrode 27, right electrode 28 and central lower back electrode 29 may be reproducibly and efficiently located by reference to the aforementioned lower back anatomical marker to optimise nerve and muscle stimulation of the gluteii. As shown in Fig. 9, the lower back anatomical marker is indicated by the reference numeral 31. Accordingly, as with the abdominal electrode arrangement described above, electrode pairs are not required and the gluteii can be stimulated employing the aforementioned three electrodes 27, 28, 29.

Fig. 10 shows a front schematic elevation of a belt 1 provided with a left electrode 15, a right electrode 16 and a central umbilical electrode 20 located on the belt 21 between the left electrode 15 and the right electrode 16. As shown in the drawing, the belt 21 is elongate in nature and is provided with a belt fastening buckle 32 device at the ends thereof. The left electrode 15, the umbilical electrode 20 and the right electrode 16 are spaced apart along the length of the belt 21. In a modification to the belt 21 of

Fig. 10, the umbilical electrode 20 can be displaced downwards on the belt 21 with respect to the left electrode 15 and the right electrode 16.

5 The belt 21 is formed from an elasticated portion 33 between the left electrode 15 and the umbilical electrode 20 and the umbilical electrode 20 and the right electrode 16 to facilitate adaptation of the belt 21 to the girth of a user 2.

10 The belt 21 is also provided with a non elasticated portion 34 between the right electrode 16 and the buckle portion 32 and a non elasticated portion 35 between the left electrode 15 and the buckle portion 32. However, if desired, the non-elasticated portions 34, 35 can be elasticated. In addition, the non-
15 elasticated portions 34, 35 can comprise length adjusting means to facilitate adjustment of the length of the belt 21. The belt 21 is contoured or shaped to define a left axillary marker 36 at the left electrode 15 and a right axillary marker 37 at the right
20 electrode 16 so that the belt 21 may be easily aligned with the respective left mid-axillary line 17 and right mid-axillary line 18 anatomical markers.

Similarly, the umbilical electrode 20 portion of the belt 21 is contoured as indicated by the reference
25 numeral 71 to identify an umbilical marker 71 for

positioning the belt 21 on a user 2 at the umbilicus 8 anatomical marker. The left axillary marker 36 and the right axillary marker 37 together with the umbilical electrode marker 71 are located on a user at clearly defined anatomical markers namely the left and right mid-axillary lines 17, 18 and the umbilicus 8.

Accordingly, a user may readily identify the anatomical markers to correctly locate the belt 21. For instance, the left and right mid-axillary lines 17, 18 may be clearly identified between the respective left and right iliac crests 6, 7 and the rib cage 3.

The belt 21 may be further provided with external markings on the belt 21 to further facilitate correct positioning of the belt 21 on the anatomical markers.

A fixed positional relationship exists between the left mid-axillary line 17 and the right mid-axillary line 18 and the umbilicus 8 in most individuals. The belt 21 can have a further elasticated downwardly disposed portion for supporting the umbilical electrode 20 so that the umbilical electrode 20 can be displaced downwards with respect to the side electrodes 15, 16 to accomodate users 2. Accordingly, the belt 21 is adapted to conform in a correct alignment with the anatomical markers in use. In

particular, the elasticated portions 33 facilitate extension of the belt 21 according to the girth of a user 2. Furthermore the umbilical electrode 20 can move elastically downwards with respect to the belt 21.

Fig. 11 shows a front schematic elevation of a belt 21 similar to the belt 21 of Fig. 10. However, in the present embodiment, the umbilical electrode 20 is formed into a central or umbilical electrode bottom portion 22 and a central or umbilical electrode top portion 23 as previously described in relation to Fig. 5.

As indicated previously, the belt 21 can be formed entirely from an elasticated material with selected areas being non-elastic as required.

The operation of the electrode 15, 16 and 20 of the belt 21 of Fig. 10 will be described having regard to Figs. 12 to 18. As shown in the drawings, the belt 21 is made up of the left electrode 15, the right electrode 16 and the umbilical electrode 13. The left and right electrodes 15, 16 are located on the left mid-axillary line 17 and the right mid-axillary line 18 in use while the umbilical electrode 20 is located in the medial position below the umbilicus 8. The

umbilical electrode 20 acts as a common return electrode 14 for current source to the left electrode 15 or the electrode 16 from a signal generator 38. The signal generator 38 is provided with a signal intensity controller 39. The left and right electrodes 15, 16 are supplied with current from one lead 72a of a lead pair 72 from the signal generator 38. The signal generator 38 is typically a single channel generator 38 where a channel is effectively an independent circuit generating an independent pulse train (as will be appreciated by those skilled in the art, a device in accordance with the present invention may have several channels each generating an independent pulse train which may be phase synchronised with other channels. Generally, the channels of a multi channel stimulator are galvanically isolated from each other to ensure that current cannot pass uncontrolled between the channels and also to provide an isolation safety barrier if one channel becomes electrically live during an electrical fault condition).

Fig. 14 shows a typical pulse pattern generated in the left and right branches of the circuit of Fig. 13. As shown in Fig. 14, the currents generated I_1 , I_2 are approximately the same in each branch of the circuit and travel to the right and left electrodes 15, 16

provided the left and right electrodes 15, 16 are of the same size and impedance - and the tissue impedance is also approximately the same. The umbilical electrode 20 forms the return electrode 14 and a
5 current, I_3 , returned from the umbilical electrode. The current returned is the sum of the currents in the branches shown namely:

$$I_1 + I_2 = I_3$$

Figs. 15 and 16 show an alternative single channel
10 stimulus signal generator 38 similar to the arrangement of Fig. 13 but where the generator is also provided with a balance control 42 for facilitating balancing of the currents I_1 and I_2 . Accordingly, the balance control 40 facilitates the proportion of
15 currents to be varied between 0 and 100%, the sum of the percentages in being 100%. Fig. 16 shows a typical illustration of the proportion of currents.

Figs. 17 and 18 illustrate a further embodiment of a signal generator for use with the left electrode 15,
20 the right electrode 16 and the umbilical electrode 20 of Fig. 12. However, in the present embodiment, the signal generator is made up of a two channel stimulator 38 in which each channel of the stimulator 38 is an independent circuit producing an independent
25 pulse train which may be, but is not necessarily,

phase off-set with respect to the other so that no two pulses coincide. The stimulator 38 is therefore provided with four terminals. Each channel is provided with an intensity control namely a left electrode
5 intensity controller 41 and a right electrode intensity controller 42. Fig. 18 shows a typical timing diagram of the current pulse pattern of each of the three electrodes 15, 16, 20. As shown in Fig. 18, the umbilical electrode 20 is formed from a current
10 pattern which is the composite of the current of the left electrode 15 and the right electrode 16.

As will be appreciated by those skilled in the art, the umbilical electrode 20 of Figs. 12 to 18 forms the return electrode 14 for the left and right electrodes
15 15, 16. However, alternatively, any one or two electrodes 15, 16, 20 could form the source electrode 13 with the remaining electrodes 15, 16, 20 acting as the return electrode 14.

In addition, the electrode array described in relation
20 to Figs. 12 to 18 may also be readily changed dynamically in real time by providing a suitable network of switches which may be semi-conductor, mechanical or electromechanical.

Therefore, it is possible to create at one or more

electrodes 15, 16, 20 of an array, and thereby in the neighbouring tissues, a current pulse train whose principal parameters of amplitude, pulse width and frequency are the sum of the corresponding parameters of other electrodes active at the same time.

Accordingly, the locus of stimulation in an array of electrodes may be varied and a tissue stimulating pattern optimised according to the tissue being targeted by a specific electrode. In contradistinction, in the method and device of Fig. 1, such an effect could only be achieved using electrode pairs in accordance with the prior art with each electrode pair driven with a different pulse train.

Figs. 19 to 25 show various electrode systems and arrays for abdominal stimulation from a left electrode 15, a right electrode 16 and an umbilical electrode 20 formed from an umbilical electrode bottom portion 22 and an umbilical electrode top portion 23.

As shown in Fig. 20, the electrodes 15, 16, 22, 23 are provided with a single channel stimulator 38 similar to the stimulator 38 of Fig. 13. As shown in the drawings, the upper electrodes of the four electrode system namely the left electrode 15, the right electrode 16 and the central electrode top portion 23 operated in unison while the umbilical electrode

bottom portion 22 functions as a common return electrode 14.

Fig. 21 shows an alternative electrode system in which the left electrode 15, the right electrode 16, the umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 are driven from the four terminals of a two channel stimulator 38 similar to the stimulator 38 of Fig. 17. In the present embodiment therefore the left electrode 15 and the right electrode 16 are driven by one channel while the umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 are driven by a second channel. Typically, the first channel and the second channel are galvanically isolated. Each channel is set in use to pulse parameters appropriate to the target muscles e.g. the rectus muscles, the transverse muscles, the oblique muscles and the like. The electrode array of Fig. 21 is effective - in particular where it is desired for the current defined between the left electrode 15 and the right electrode 16 to penetrate deeply into abdomen tissue or the like. However, where such deep penetration is not required the electrode array of Fig. 22 described below is preferred.

As shown in Fig. 22, the electrode array is provided

with two channels as described in relation to Fig. 21. However, in the present embodiment, a first channel is employed to drive the left electrode 15 and the right electrode 16 with respect to the umbilical electrode bottom portion 22 (the return electrode 14).

Meanwhile, the second channel is employed to drive the umbilical electrode top portion 23 with respect to the umbilical electrode bottom portion 22. Accordingly, no transabdominal current path is generated while each of the electrodes of the array is adapted to create current density in the tissue located beneath the electrodes.

As indicated above, the relative current density may be controlled by intensity controllers such as a transverse muscle intensity controller 43 and a rectus muscle intensity controller 44.

In the present invention the umbilical electrode 20 can have a surface area up to the sum of the surface areas of the left and right electrodes 15, 16 so that, depending on the current pulse sequences employed, the current density at the umbilical electrode 20 will be approximate the current density at the left and right electrodes 15, 16. If the area of an electrode, such as the umbilical electrode 20 is too small, over stimulation of a muscle group at that electrode can

result.

Fig. 23 shows a schematic representation of the left electrode 15 (designated L) the right electrode 16 (designated R) the umbilical electrode bottom portion 22 (designated U_1) and the umbilical electrode top portion 23 (designated U_2) as applied to an abdomen 5. Possible current paths between the electrodes are indicated in Fig. 23 using the appropriate letter i.e. the appropriate electrode pair involved and numbered appropriately with Roman numerals. For example, the current path in the abdomen between the electrodes L and R is labelled RL and is numbered VI in the illustration. In accordance with the present invention, the current path identified in Fig. 23 may be used either alone or in isolation for optimum and efficient muscle stimulation to achieve desired results. In order to obviate transabdominal current paths, LR, the L and R electrodes are employed as sources with U_1 and U_2 connected together to form a return electrode. Accordingly, current paths I, II, III and IV provide stimulation over a comparatively broad area of the abdomen. The U_1 and U_2 connections may then be separated and a current path between U_1 and U_2 generated to create a current path $U_1 U_2$ which, in the present example, can boost stimulation of the rectus muscle.

Fig. 24 shows a typical circuit arrangement employing switches to achieve the combination of current paths described in Fig. 23. As shown in Fig. 24 the electrode array is provided with three switches S_1 , S_2 , S_3 , controllable by a system microprocessor, (not shown), to control current generation. The switches S_1 , S_2 and S_3 may be relays or semi-conductor circuits. When S_1 and S_2 are closed and S_3 is in the (open) lower position (b) shown in Fig. 24, then current paths I, II, III and IV are enabled. However, with switch S_3 in the upper (b) position the current path V is enabled. Accordingly, through manipulation of the switches S_1 , S_2 and S_3 , each pulse in a sequence may be easily directed to a specific current path.

Fig. 25 shows a schematic representation of an array of the invention for controlling current to and between electrodes in electrotherapy e.g. to the left and right electrodes 15, 16 and the umbilical electrode bottom portion 22 and the umbilical electrode top portion 23 hereinbefore described. A first pulse generator 46 and a second pulse generator 47 are in communication with an array of cross point switches, $S_1 - S_{16}$, under the control of a microprocessor (not shown). More particularly, the first pulse generator 46 is in communication with an array of eight switches, $S_1 - S_8$ and the second pulse

generator 47 is in communication with eight switches S_1 - S_{16} . As shown in Fig. 25, the electrodes 15, 16, 22, 23 and the first and second generators 46, 47 define two stimulator channels which may be galvanically isolated from each other. In order to create the current paths III and IV, switches S_2 , S_4 , S_5 of Fig. 25 are closed.

It will be appreciated by those skilled in the art that the switches S_1 - S_{16} may be relays or semiconductor circuits. Alternatively, the switches S_1 - S_{16} may be manually operated.

The microprocessor (not shown) can select on a pulse by pulse basis the current path to be taken by each pulse. Accordingly, the current distribution and effective pulse frequency at each electrode can be optimised for the tissues it is desired to stimulate. Clearly, the array of Fig. 25 can find application in many electrotherapeutic devices - those of the present invention and indeed devices of the prior art such as those described in Fig. 1.

Figs. 26 to 35 show various embodiments of an electrode placement device in the form of a belt provided with protective and reusable release sheets for protecting the electrodes 15, 16, 20, 22 and 23

herein before described. As shown in Fig. 26a, an umbilical electrode 20 formed from an upper umbilical electrode portion 23 and a lower umbilical electrode portion 22 on the belt 21 is provided with an

5 outwardly and laterally extending release sheet 48 disposed above and below the upper umbilical electrode portion 23 and lower umbilical electrode portion 22. The release sheet 48 for each of the said electrode portions 23, 22 is foldable along a fold line 50

10 continuous with the outside edges of the belt 21 so that each release sheet 48 is foldable inwards towards the respective upper umbilical electrode portion 23 and lower umbilical electrode portion 22 to protect the electrode portions 22, 23. The method of folding

15 the release sheets 48 is indicated by arrows in Fig. 26a.

Fig. 26b also show an umbilical electrode 20 provided with two release sheets 48 extending laterally outwards from the belt 21. However, in the present

20 embodiment, the umbilical electrode 20 is not subdivided into an upper umbilical electrode portion 23 and a lower umbilical electrode portion 22. Accordingly, in the present embodiment, the release sheets 48 are foldable inwards along the fold line 50

25 to protect and cover the single umbilical electrode 20.

Alternatively, the double release sheets 48 of Figs. 26a and 26b could be formed from a single release sheet attached to one edge of the belt 21.

Fig. 27 shows an alternative embodiment of a belt 21 in accordance with the invention provided with release sheets 48 on the internal surface of the belt 21. In particular, each of the left and right electrodes 15, 16 and the umbilical electrode 20 disposed on the inner surface of the belt 21 are provided with
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respective complementary release sheets 53, 52 and 51 also on the internal face of the belt 21 for abutting the respective electrodes 15, 16, 20 upon folding of the belt 21.

Fig. 28 shows an alternative embodiment of a belt 21 in accordance with the invention in which the umbilical electrode extends laterally outwardly downwards when in use from the belt 21 but is nevertheless foldable along a fold line 49 defined at the outside edge of the belt 21. The umbilical
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20
electrode 20 is foldable such that the electrode 20 is contacted with the outer surface of the (anatomical) back portion of the belt 21 to protect the electrode surface.

Fig. 29 shows a further embodiment of a belt 21 in

accordance with the invention in which the left electrode 15, the right electrode 16 and the umbilical electrode 20 are spaced apart on the belt 21 by intermediate respective release sheets 56, 58 and 57.

5 The belt 21 is transversely foldable along an axis disposed vertically with respect to the central longitudinal axis of the belt 21 at a fold line 55. Accordingly, folding of the belt 21 along the fold line 55 causes the release sheet 56 to be urged
10 against the left electrode 15, the release sheet 58 to be urged against the right electrode 16 and the release sheet 57 to be urged against the central umbilical electrode 20 to protect the electrodes when the belt 21 is not in use. As shown in the drawings,
15 each release sheet 56, 57, 58 is attached to the belt 21 by a mounting pin 54. The release sheets 56, 57, 58 are reversibly mounted on the belt 21 by the pins 54 so that the release sheets may be replaced as required.

20 Fig. 30 shows an alternative arrangement of the belt 21 showing sheets 56, 57, 58 and the respective electrodes 15, 16 and 20 of Fig. 29.

Fig. 31 shows an alternative belt 21 in accordance with the invention in which the release sheets 56, 57,
25 58 are disposed between the electrodes 15, 16 and 20

as previously described. However, in the present embodiment, the release sheets 56, 57, 58 are hingedly mounted the belt 21 by respective hinge mountings 59, 60 and 61 so that the release sheets 56, 57 and 58 are
5 movable between an electrode protecting position and an electrode exposing position about the respective hinges 59, 60, 61. The belt 21 is foldable along the line 55 as previously described. Provision of hinged non-elasticated release sheets 56, 57, 58 ensures that
10 the elasticity of the belt 21 is not compromised by the release sheets 56, 57, 58. As shown in the drawing, the hinges are located on the release sheets to minimise shearing forces. Accordingly, the hinges are located towards the outer or distant edge of each
15 release sheet 56, 57, 58 with respect to the central umbilical electrode 20.

Figs. 32 and 33 show an alternative belt 21 in accordance with the invention in which the left electrode 15, the right electrode 16 and the umbilical
20 electrode 20 are spaced apart on the belt 21 as previously described. However, in the present embodiment, the respective release sheets 56, 57, 58 disposed between the electrodes are integral with the belt 21 i.e. the material of the belt 21 is adapted to
25 define integral release sheets. Accordingly, as shown in Fig. 33, the belt 21 is foldable such that the

integral release sheets 56, 57, 58 define opposing mating faces in the folded position with the respective electrodes as previously described.

Naturally the release sheets 56, 57, 58 could also be
5 non-integral release sheets as hereinbefore described.

Fig. 34 shows an alternative arrangement of belt 21 in accordance with the present invention in which the left electrode 15 and the right electrode 16 are located on the internal face of the belt 21 as
10 previously described. However, in the present embodiment, the left electrode 15 and the right electrode 16 are separated by three release sheets on the belt 21 namely release sheets 63, 64 and 65. The central umbilical electrode 20 is disposed laterally
15 downwardly and outwardly from the belt 21 opposite to the central release sheet 64. Accordingly, the belt 21 is foldable such that the left electrode 15 is matable against the release sheet 65, the right electrode 16 is matable against the release sheet 63 while the
20 umbilical electrode 20 is foldable upwards against the central release sheet 64.

Fig. 35a shows an alternative arrangement of a belt 21 in accordance with the invention in which the left electrode 15 and right electrode 16 and umbilical

electrode 20 are arranged substantially as described in relation to Fig. 34. As shown in Fig. 35a, in one mode of operation of the belt 21 of Fig. 35a, the umbilical electrode 20 is folded upwards along the fold line 70 towards a central release sheet 75 disposed between a second release sheet 67 and a third release sheet 68 similar to the first release sheet 63 and the third release sheet 65 of Fig. 34. Accordingly, the central release sheet 75 is equivalent to the second release sheet 64 of Fig. 34. In order to affect mating of the electrodes with the releases sheets, the electrode 20 is folded about the fold line 70 against the central release sheet 75 as described above. The belt 21 is then folded about a fold line indicated by the reference numeral 69 disposed transversely to the fold line 70 so that the right electrode 16 is mated against the release sheet 68 and the left electrode 15 is mated against the release sheet 66.

Alternatively, where the umbilical electrode 20 is of increased area and impinges upon the area occupied by the central release sheet 75 in Fig. 35a, the release sheet 67 may be a hinged release sheet similar to the hinged release sheets previously described. However, in the present embodiment, the release sheet 67 is disposed parallel to the fold line 69 at the proximate

end of the release sheet 67 adjacent the central release sheet 75 in Fig 35a. Accordingly, in order to effect mating of release sheets with the electrodes in the present embodiment, the release sheet 67 is first
5 hinged about the hinge 76 to occlude the area of the "release sheet" 75. The dependent umbilical electrode 20 is then folded about the hinge 70 onto the turned over release sheet 67. The belt 21 is then folded as indicated above for the belt 21 of Fig. 34.

10 Fig. 36 shows an alternative embodiment of a belt 21 in accordance with the invention. The belt 21 of Fig. 36 is broadly similar to the belt of Fig. 35a i.e. the umbilical electrode 20 extends into the area occupied by the central release sheets 75 of Fig. 35a. In order
15 to effect closing of the belt 21 of Fig. 36, the belt 21 is first folded at the fold line 69 indicated in Fig. 35a. The dependent umbilical electrode 20 is then folded along the fold line 70 to mate against the back or reverse of the belt 21 i.e. on the reverse side of
20 the belt 21 contiguous with the area occupied by the release sheet 67 in Fig. 35a. Accordingly, the dependent central umbilical electrode 20 is protected by the reverse face of the belt 21.

The invention also provides an array for a controller
25 for electrotherapy in accordance with the invention in

which a plurality of current pulses may be applied to the electrodes and in turn muscles for stimulation in various permutations and combinations according to the arrangement of switches employed in the array.

5 Therefore, the array facilitates the use of various pulse types to effect stimulation of muscles.

As indicated above, the release sheets herein described may be located on the inner or outer surface of the belt 21 and may be integral with or attached to
10 the belt 21. In addition, the release sheets may extend laterally outwardly from the belt 21 and may be foldable with respect to the belt 21.

The release sheets herein before described do not interfere with stretching of the belt 21 of the
15 invention in order to accommodate a user 2. In one embodiment of the invention, the release sheet of the belt 21 may be of elastic or plastics material while, where desired, the release sheets may be adapted to be inelastic at desired locations on the belt 21 to
20 control elasticity of the belt 21.

In an alternative embodiment of the invention, the electrodes of the belt 21 may be oriented and spaced apart along the belt 21 to share a common release sheet attached to the belt 21.

Moreover, as indicated above, the belt 21 may be adapted to define or comprise integral release sheets for protection of the electrodes.

In an alternative embodiment of the invention, the
5 umbilical electrode 20 can be found on a stiffened portion of the belt 21 to prevent curling of the umbilical electrode 20. Moreover, the umbilical electrode 20 can be located on the reverse or rear of a portable control unit integral with or mountable on
10 the belt 21. The electrodes 15, 16, 20 and in particular the central lower back electrode 29 can be found from a resiliently deformable material to adapt to the shape of an individuals anatomy e.g. the concave shape of the lower back.

15 In another embodiment of the invention, the electrode surfaces may be framed with an area that will attach to an adhesive gel of the electrode relatively strongly e.g. in this case the gel-pad area is larger than the electrode area. In another embodiment of the
20 invention, the planar surfaces of the gel electrode layer may have different tactile properties. For example, a designated, relatively adhesive side may be attached to the electrode surface. In a still further embodiment of the invention, the replacement gel-pad
25 skin contact surface may be framed at its perimeter

with a single sided adhesive tape. The adhesive side may be in contact with the outer margin of the gel while the tape extends around the margin of the gel. For example, the tape may also share a common release
5 sheet with the electrode contact side of the gel-pad while upon removal of the (inner) release sheet, the combined pad-tape unit may be firmly applied to the inner belt/electrode surface. Use of the adhesive tape minimises risk of the gel-pad fraying at the edges,
10 moving in use or becoming dislodged from its designated site. However, it is not necessary for the tape element to extend about the entire periphery of the gel-pad. For example, the tape element may simply include or protect selected edges or corners.

15 In a still further embodiment of the invention, the belt 21 may be provided with a recess or a raised area ensuring proper positioning and locating of electrodes. The raised area may be a plateau for direct electrode pad placement or a raised ridge
20 framing the surface for electrode pad placement. The recess may be adapted to comprise suitable dimensions. The recess may also be adapted to define a cleft-like depression. The cleft may be dimensioned to accommodate the electrode gel-pad edges or selected
25 edges only. The provision of such a recess ensures that shearing forces on the electrode pad surface are

unlikely to lift the electrode gel pad from its designated locus.

In a still further embodiment of the invention, the periphery (or selected outer margin) of the skin
5 contacting electrode gel pad may have reduced adhesive properties. The periphery or selected outer margins may have the reduced adhesive properties by coating or covering the periphery or the selected outer margins with suitable material. Accordingly, shearing forces
10 on the electrode surface are unlikely to lift the electrode pad from its designated locus.

In a still further embodiment of the invention, the edges or selected edges of the electrode pad may be sloped. In this embodiment of the invention, the non
15 sloped portion of an electrode may be designated as an electrode contacting surface so that shearing forces on the electrode surface are less likely to lift the electrode from its designated locus.

It is also envisaged in an alternative embodiment of
20 the invention that the edges, or selected edges of the gel-pad may be held in position by flaps, clips, tabs and the like.

As indicated previously, a user 2 positions a first

marker on the belt 21 at an anatomical marker e.g. the mid-axillary lines 17, 18 or the umbilicus 8 as appropriate and subsequently stretches the belt to the next anatomical marker and, if available, further anatomical markers for closing the belt 21. The belt 21 can be tightened, if necessary at the buckle 32 in a manner similar to airline safety belts or by utilising overlapping velcro surfaces as the fastening method.

- 10 The belt 21 is applied in a wrapping motion which has the effect of bringing each electrode into contact with the skin in a direction which is normal to the skin surface thereby avoiding shearing movement which tends to wrinkle electrode surfaces - especially when
- 15 the electrodes are adhesive faced.

For example, where the electrode placement device in accordance with the invention is an abdominal belt 21 as previously described, the preferred method of mounting the belt 21 on a user 2 is to align the

20 abdominal marker while the belt is held fully extended. Each end of the belt is then brought back posteriorly, stretching as necessary to align the mid-axillary line marker and the belt 21 is finally closed and possibly tightened at the posterior.

In one embodiment of the invention, the belt 21 is provided with electrodes in the form of rubber pads mounted on the inner surface of the belt 21. The belt 21 may be connected to a generator unit 38 as

5 previously described by wires integrated within the belt by means of an inserted pin or clothing fastener. Conductive electrodes may be attached to the belt 21 by gluing, vulcanising, sewing, clamping or the like. Within the belt, current may be distributed through

10 longitudinal stripes formed by conductive fibres separated by stripes of insulating material which are used to pass current between the generator 38 and the electrodes. Suitably, conductive flexible material may be employed at designated points on the inner surface

15 of the belt 21 to connect the conductor stripes to the skin, the patches of conductive material being so placed at the one designated conductive stripe. The conductive flexible material may be fabric, metal foil, carbon loaded film, hydrogel, fluid filled

20 sponges or the like. The conductive stripes may be covered by insulation except in specific localised areas where the conductive stripes are exposed without contact with the skin directly or indirectly by means of a patch of flexible conductive material or

25 conducted fluid.

Accordingly, in use, a user 2 simply holds the .

extended belt 21 in a substantially horizontal disposition with one end at each of the belt 21 adjacent the buckle 32. The user 2 then urges the belt 32 towards the abdomen 5 such that the umbilical electrode 20 of the belt 21 approximates to the umbilicus 8. The user 2 then moves the buckle 32 at the ends of the belt 21 posteriorly to locate the left and right electrodes 15, 16 along the respective mid-axillary lines 17, 18 before finally closing and fastening the belt 21 with the buckle 32. The elasticated portions 33 of the belt 21 ensure that size difference between subjects can be accommodated.

It should be appreciated that the buckle 32 of the belt 21 of the invention may be formed from a plastics buckle, velcro or the like.

The method of use of the belt 21 ensures the approximation of the adhesive surface gel electrodes to the skin in a direction substantially normal to the skin surface thereby avoiding shearing movements.

The advantages of the invention are many. The invention facilitates the accurate placement of electrodes on the skin to ensure that stimulation currents for electrotherapy purposes are confined to the target area and are delivered at the most

effective loci. Furthermore, the belt device of the invention facilitates the application of moderate pressure over the surface of an electrode in contact with the skin thereby reducing electrical impedance of the skin-electrode contact to maximise efficiency. Although the applicants do not wish to be bound by any theorem, it is believed that impedance is reduced due to enhanced contact of the semi-fluid electrolyte of the conductive medium of the electrode with the microscopic uneven surface of the skin.

The present invention therefore provides a belt device which incorporates a plurality of electrodes fixed to the belt and which can be fitted around the girth, limbs etc of the body to locate on easily identifiable anatomical markers. The device of the invention may be adapted for use on various anatomical parts such as the abdomen, buttocks, limbs and like. The position of the electrodes within the belt ensures that when the belt is correctly aligned with obvious anatomical markers that the electrodes are then automatically aligned correctly with the target's given location. The device and method of the invention is also adapted to minimise the risk of transabdominal and transthoracic current flows by passing current by lateral electrodes to more centrally located electrodes. For example, where the device and method

of the invention is employed for abdominal muscle stimulation, central electrodes are placed on the skin overlying the rectus abdominis muscle (adjacent the umbilicus) and stimulation of the rectus abdominis is
5 achieved in addition to the oblique muscles and the transversalis muscles. In addition, such an electrode arrangement allows for a reduction in the total number of electrodes e.g. from as many as eight to three or four electrodes.

10 In addition, incorporation of the electrode positions in accordance with the invention into a "wired" belt - like structure ensures proper orientation of the electrodes and precludes the possibility of inadvertent sending of current in a potentially
15 hazardous direction such as deep into tissues. Moreover, elastication of the belt of the present invention facilitates use of the belt type arrangement with users of varying sizes.

The method and apparatus of the invention has
20 particular application in the application of electrical current to abdominal and gluteii muscles. In addition, the method and device of the invention may be employed in the stimulation of lower back musculature.

The method and device of the invention is suitable for use with various types of electrodes such as gel adhesive or carbon - rubber electrodes.

5 The provision of a belt - type device incorporating electrodes in accordance with the present invention eliminates loose wiring, incorporates electrode protection and allows for rapid and accurate electrode placement.

10 The invention also provides an array for a controller for electrotherapy in accordance with the invention in which a plurality of current pulses may be applied to the electrodes and in turn muscles for stimulation in various permutations and combinations according to the arrangement of switches employed in the array.

15 Therefore, the array facilitates the use of various pulse types to effect stimulation of muscles.

In addition, the present invention eliminates the requirement of a separate wiring system, cover and backing in gel - type electrodes. Finally, the use of
20 removable release sheets in combination with gel - type electrodes ensures protection of the electrode and prolongs the longevity of the electrode.

The invention is not limited to the embodiments herein described which may be varied in construction and detail.

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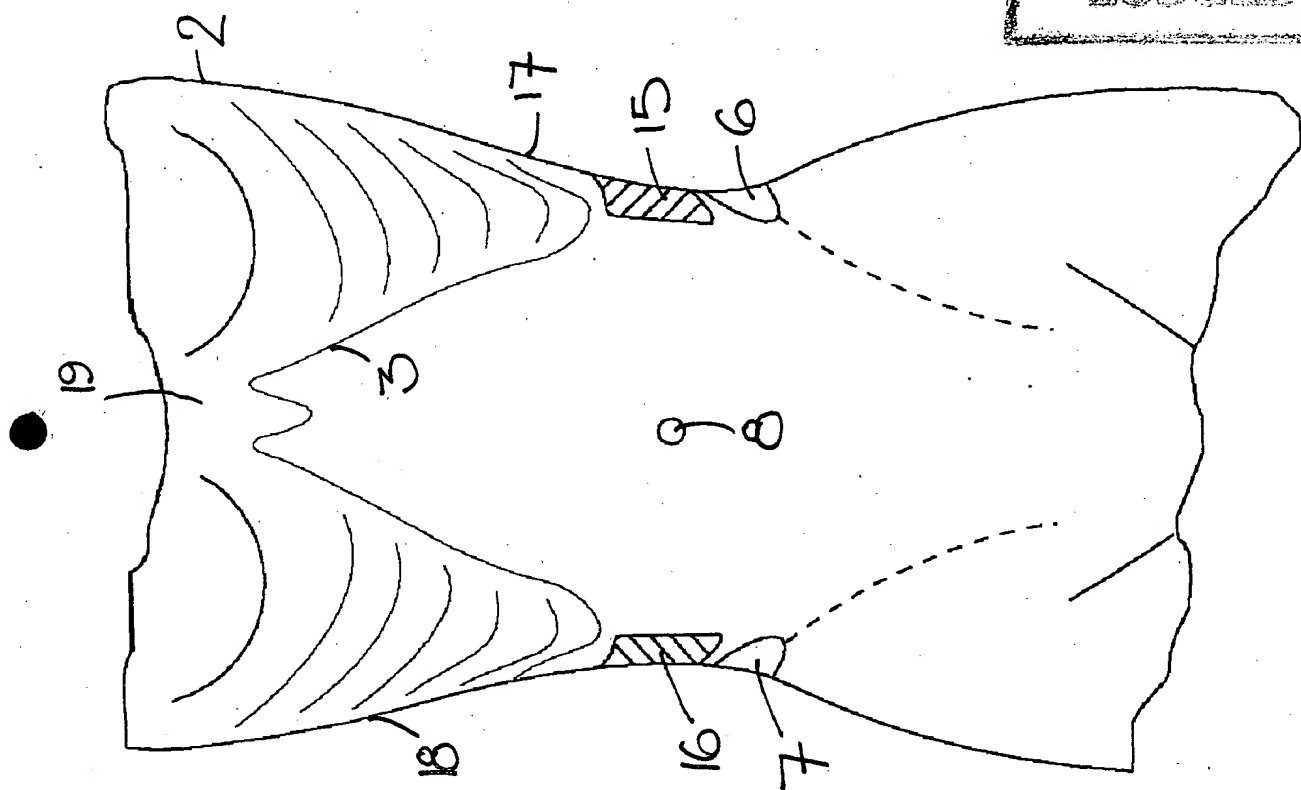


Fig. 2

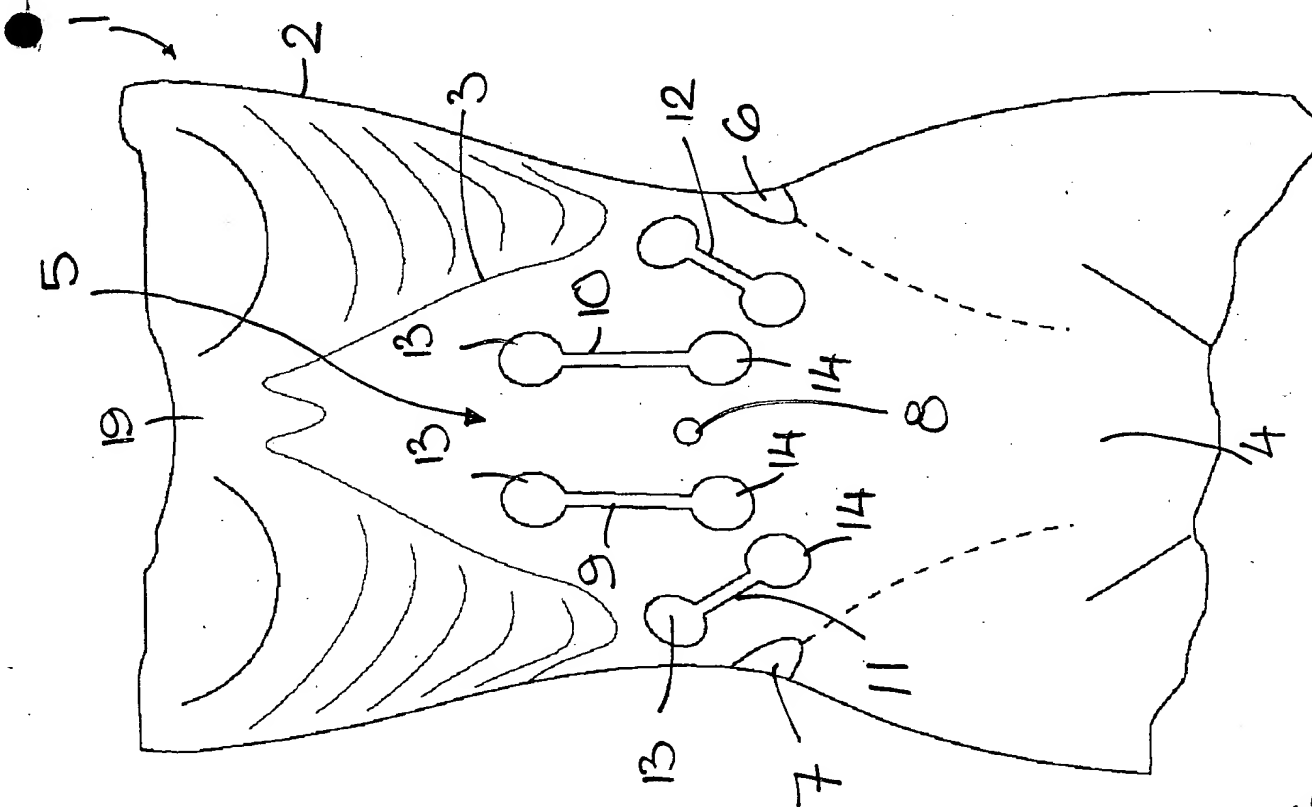


Fig. 1

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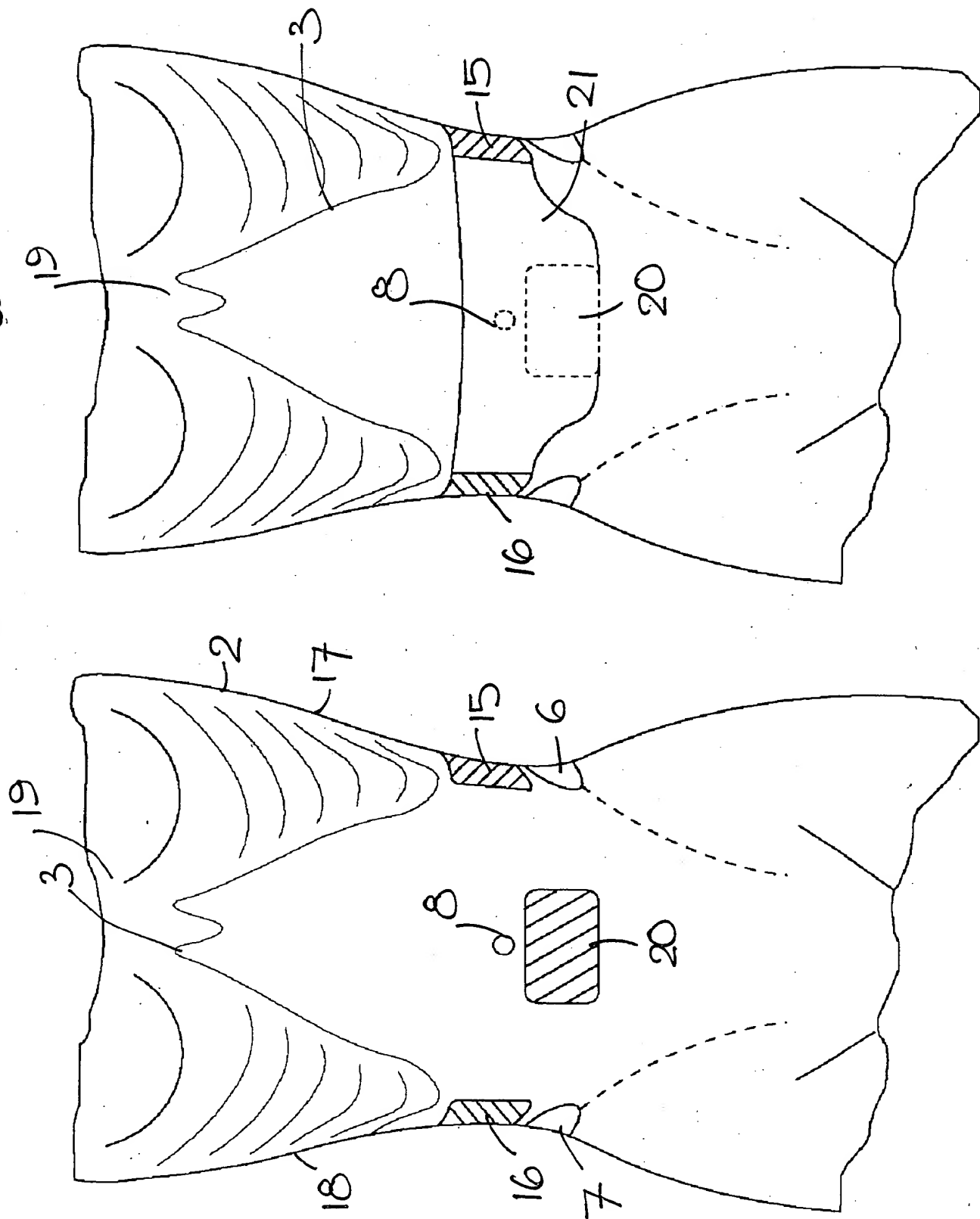


FIG. 4

FIG. 3

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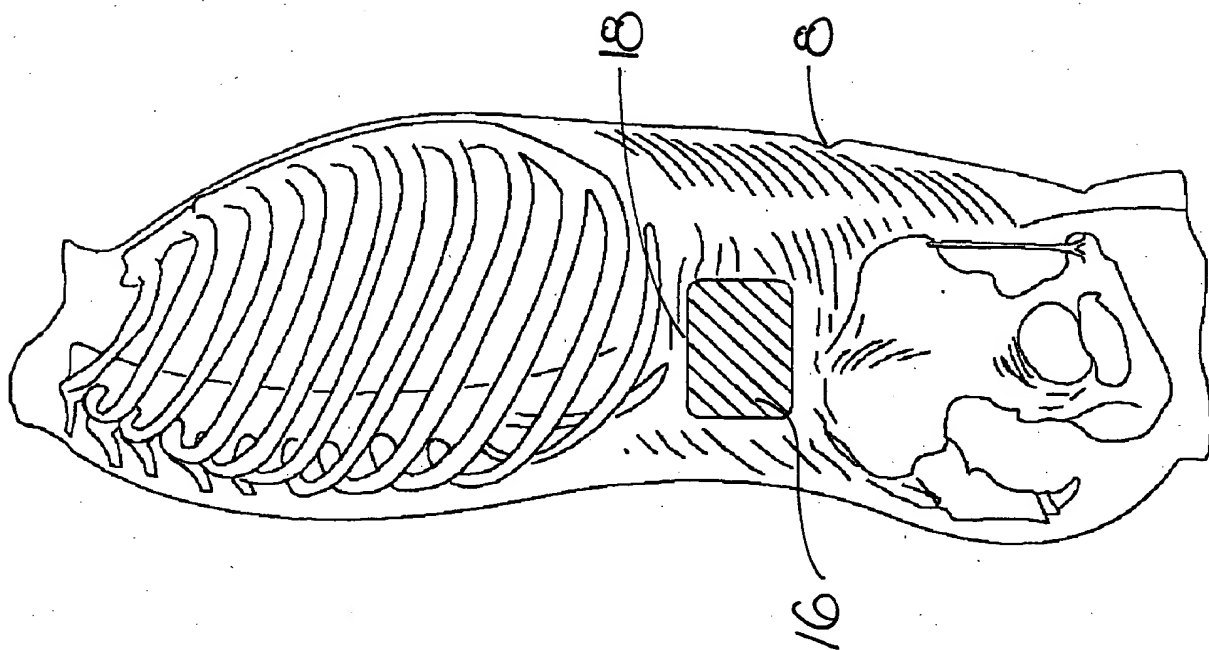


Fig. 6

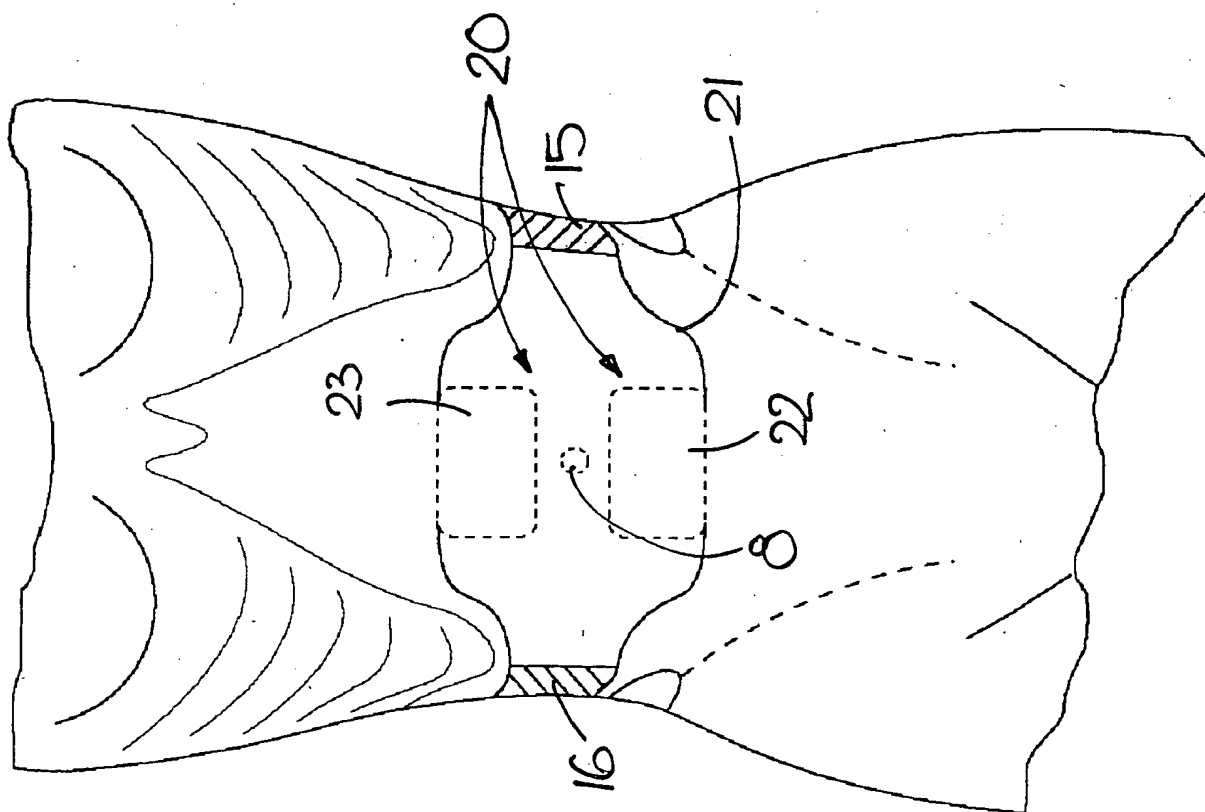


Fig. 5

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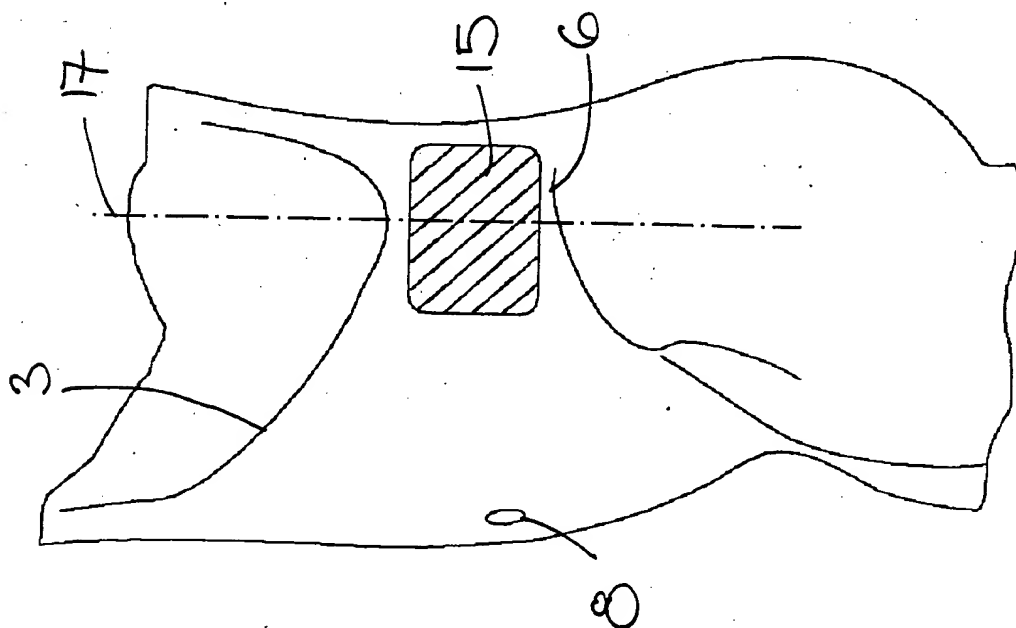


Fig. 7

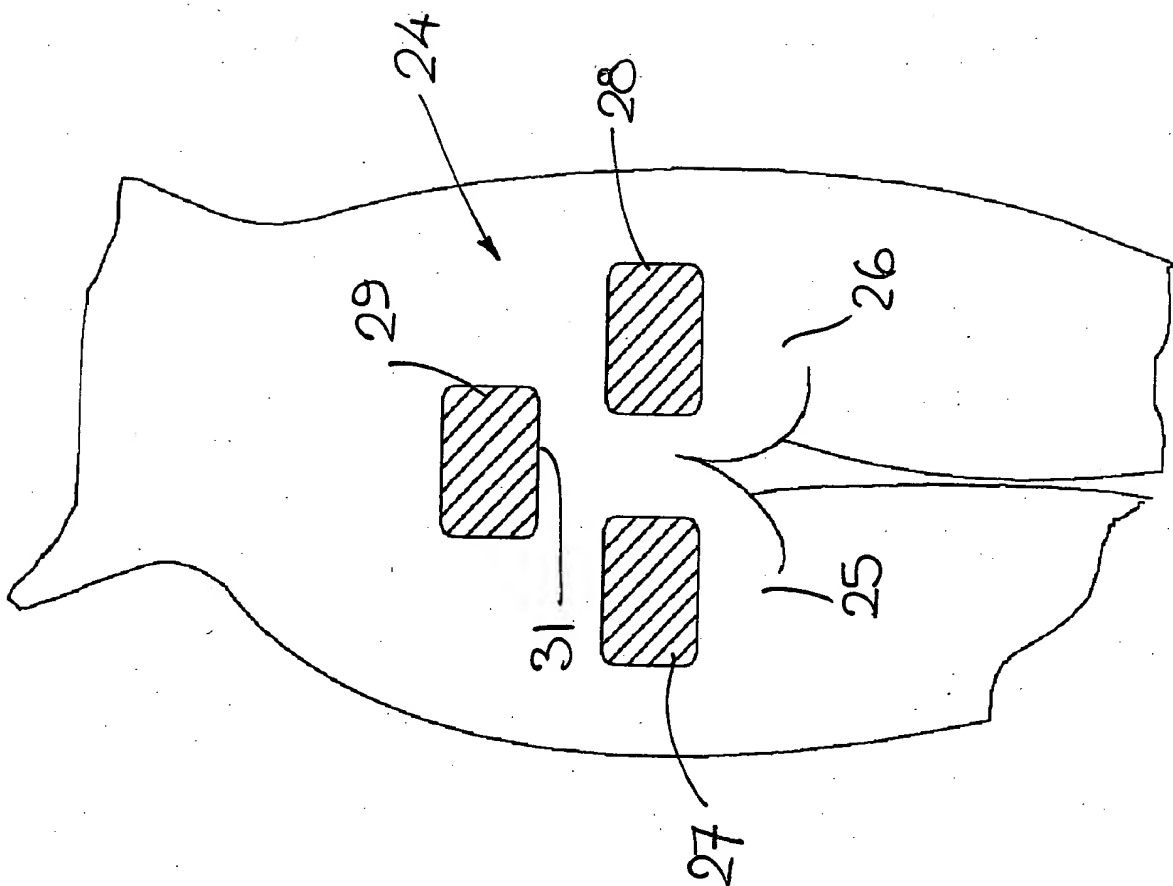


Fig. 8

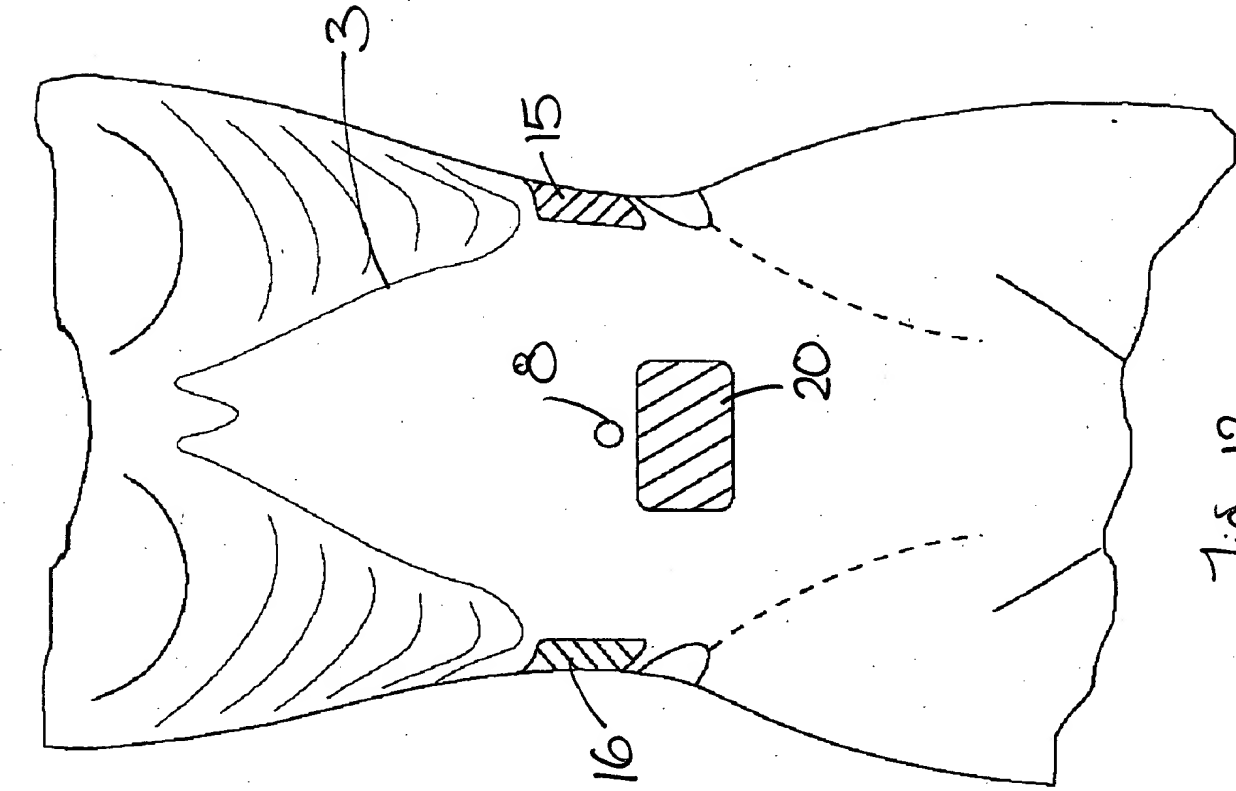


Fig. 12

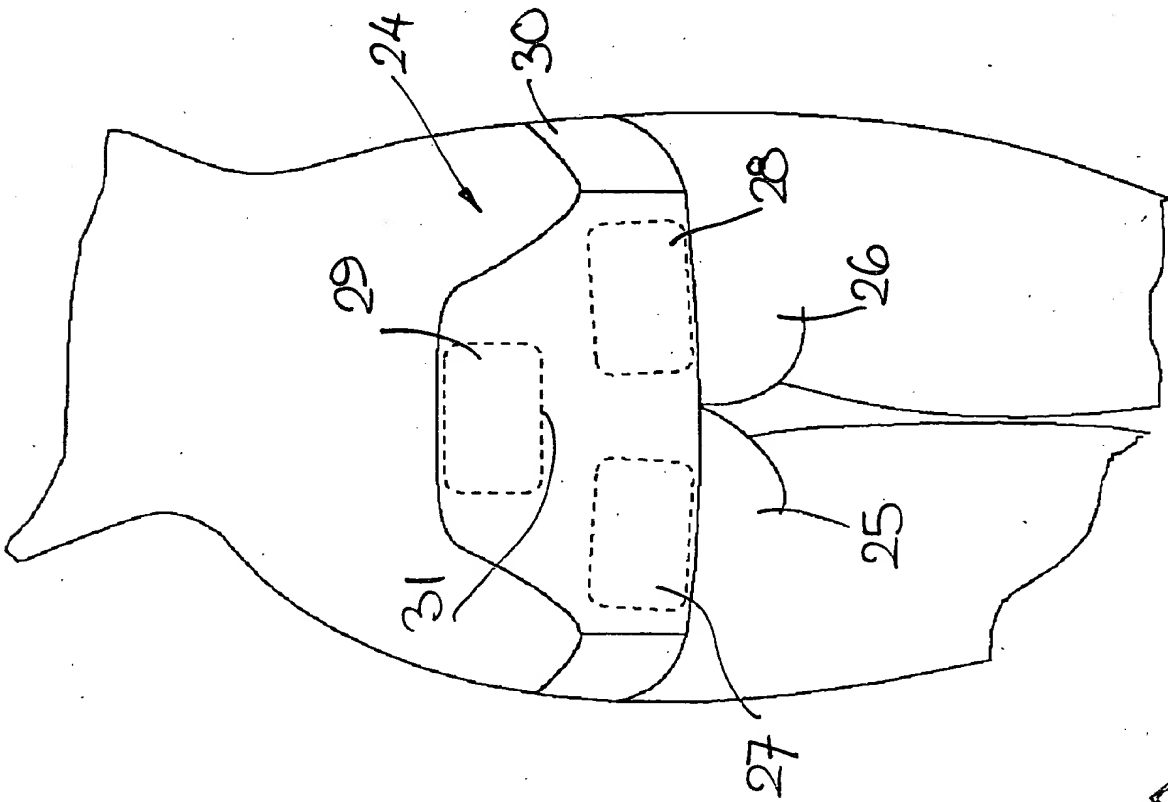
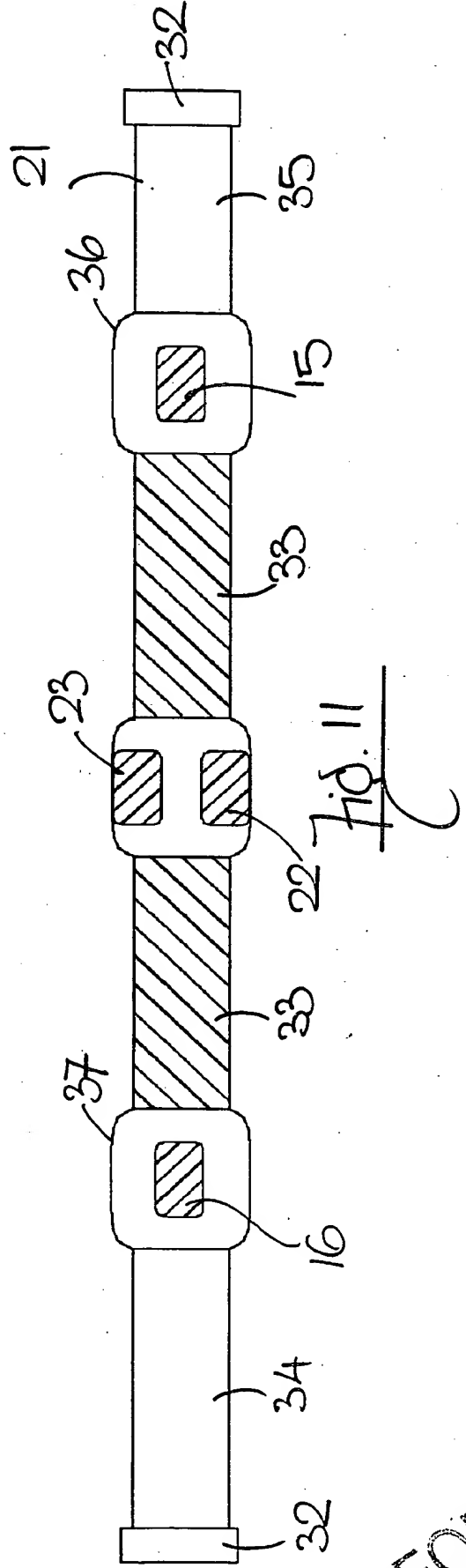
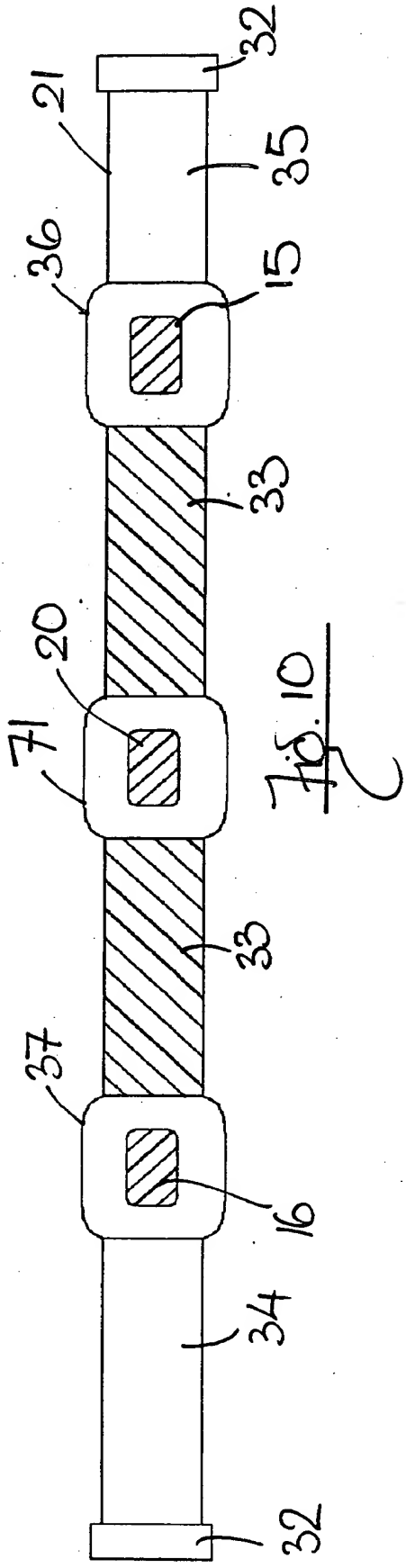


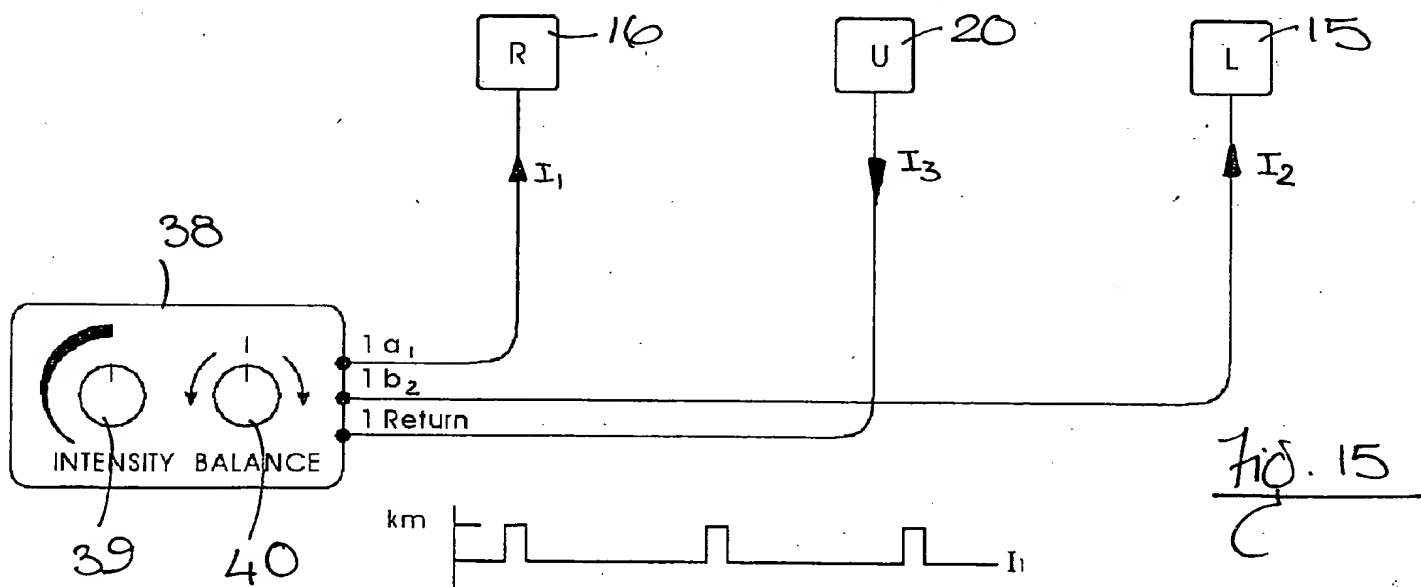
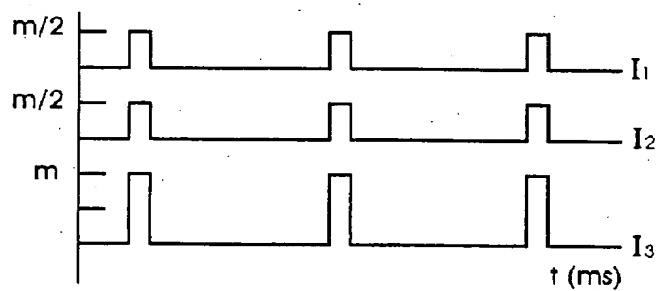
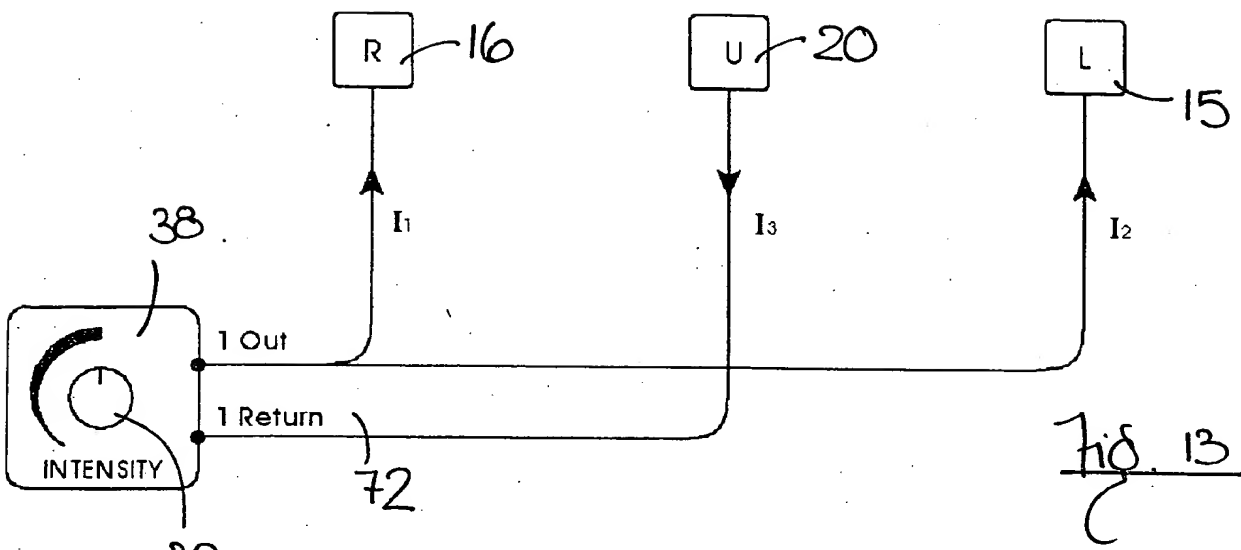
Fig. 9

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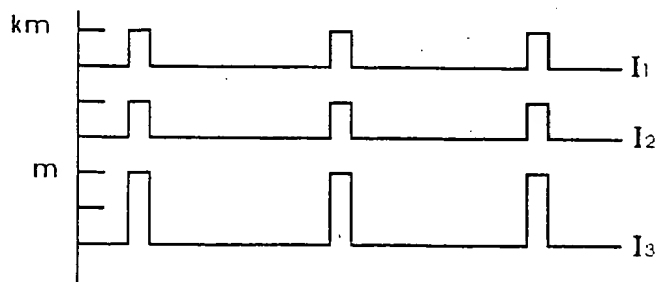


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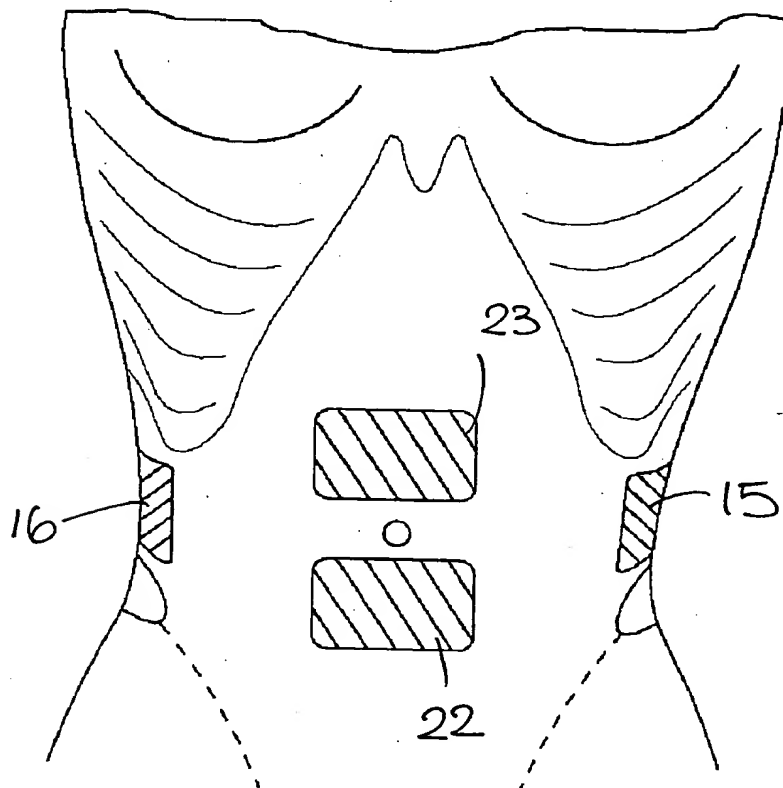
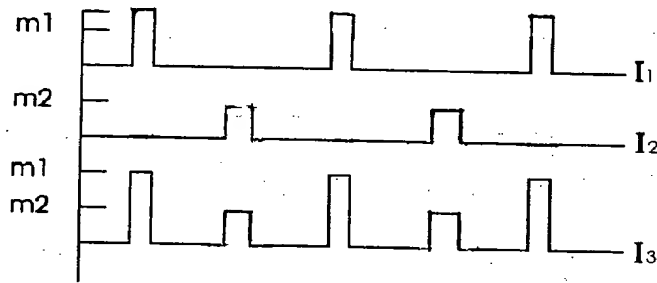
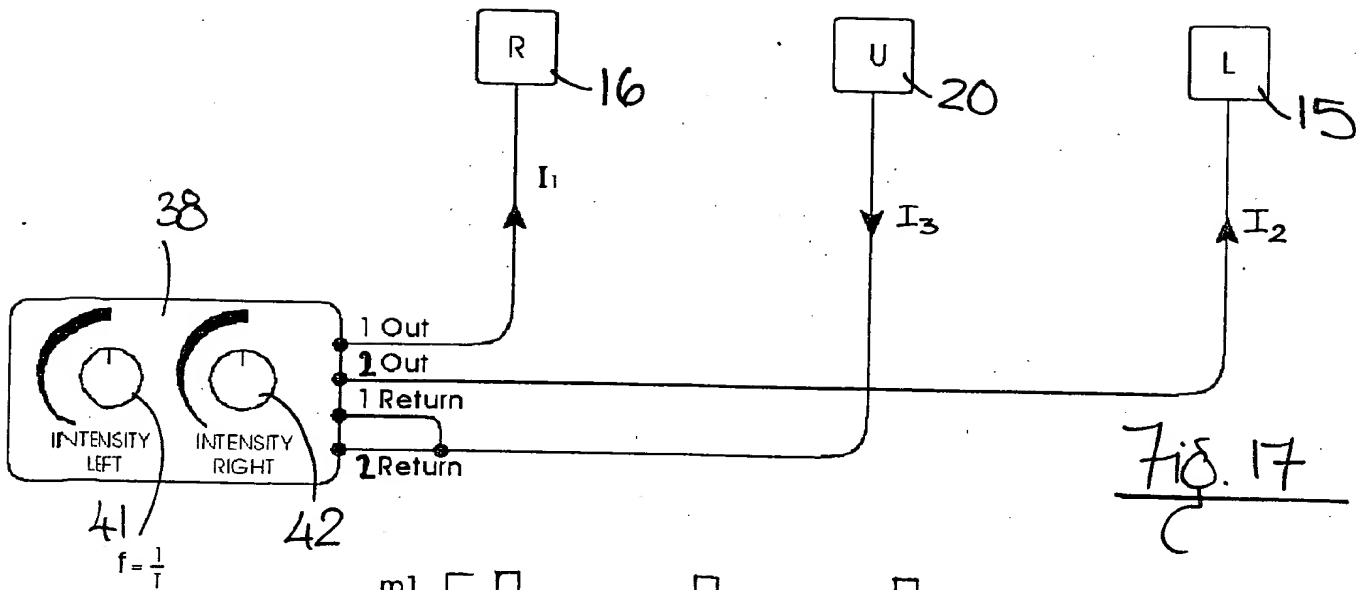


$(1-K)m$
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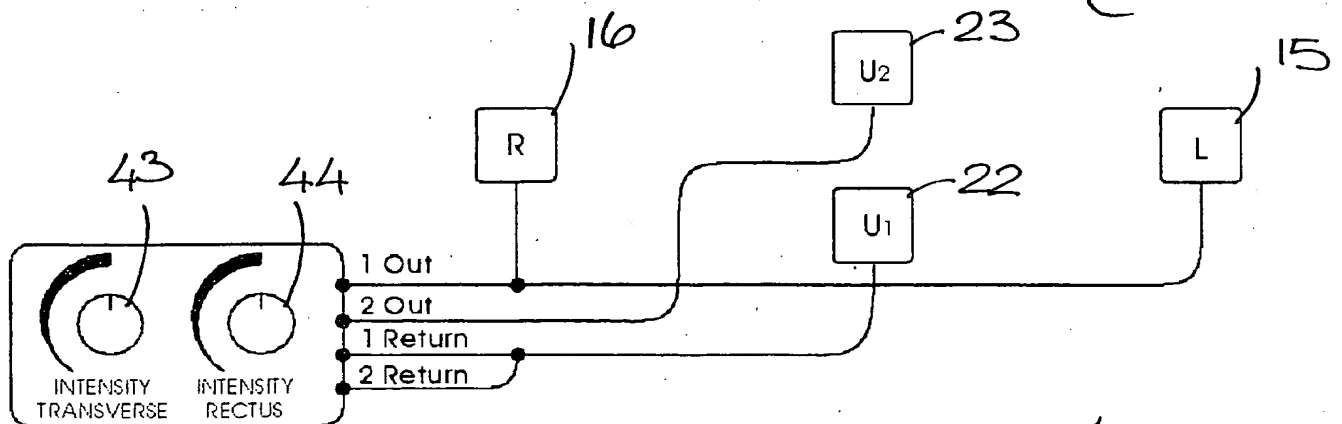
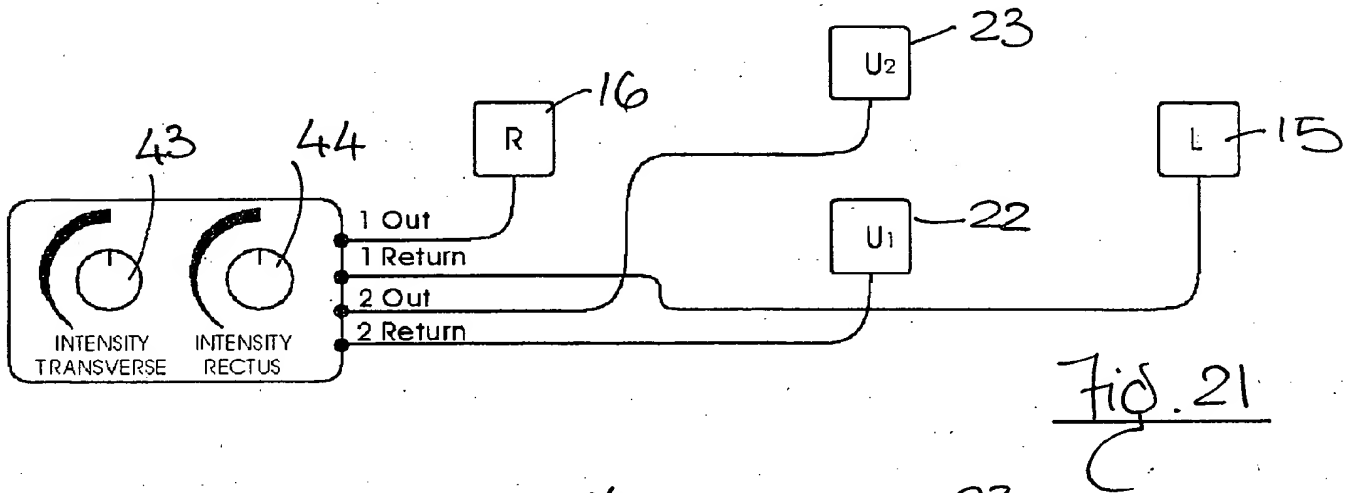
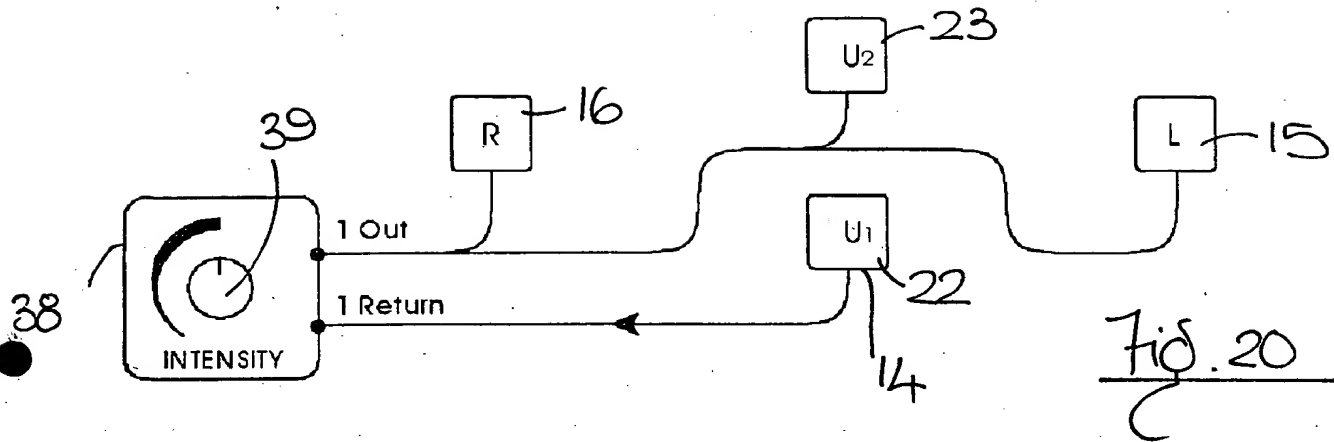


Fig. 22

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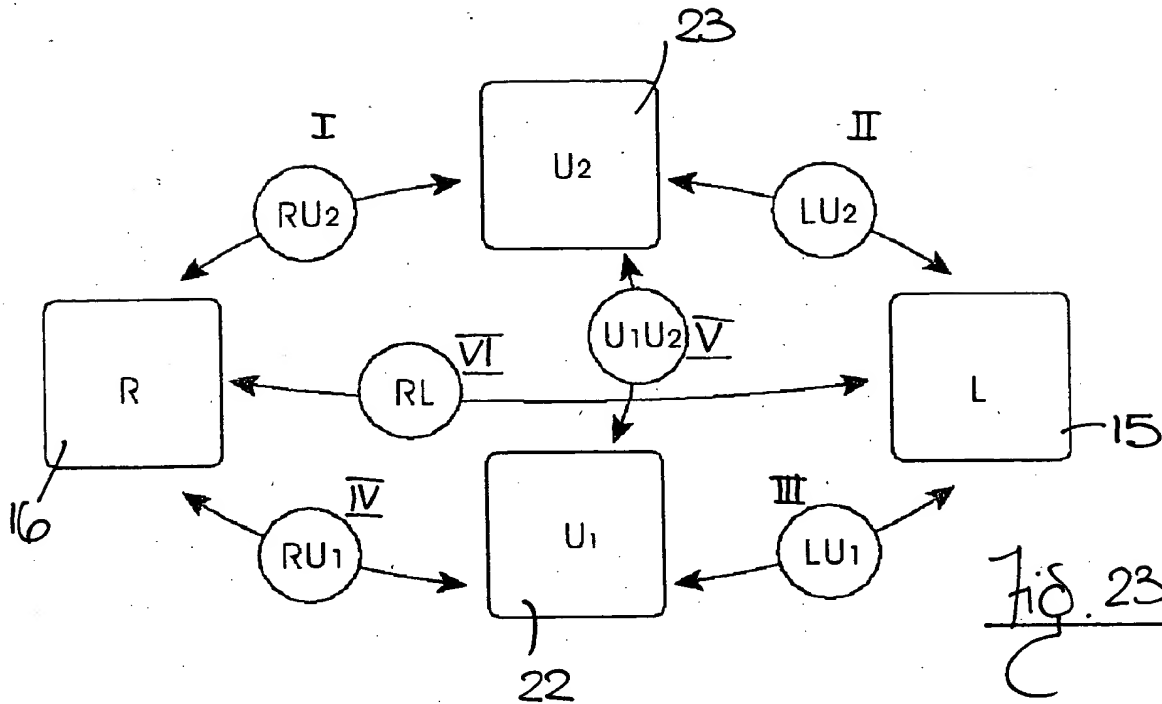


Fig. 23

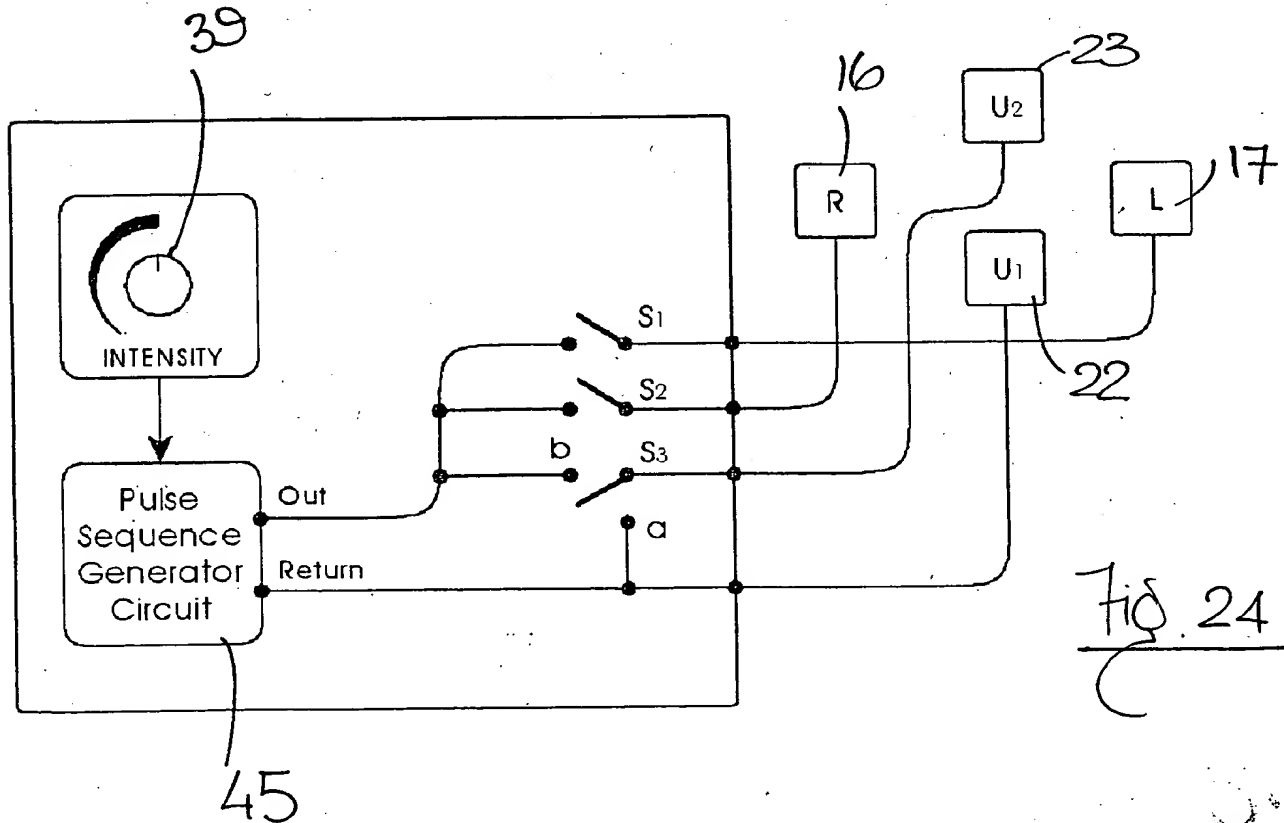


Fig. 24

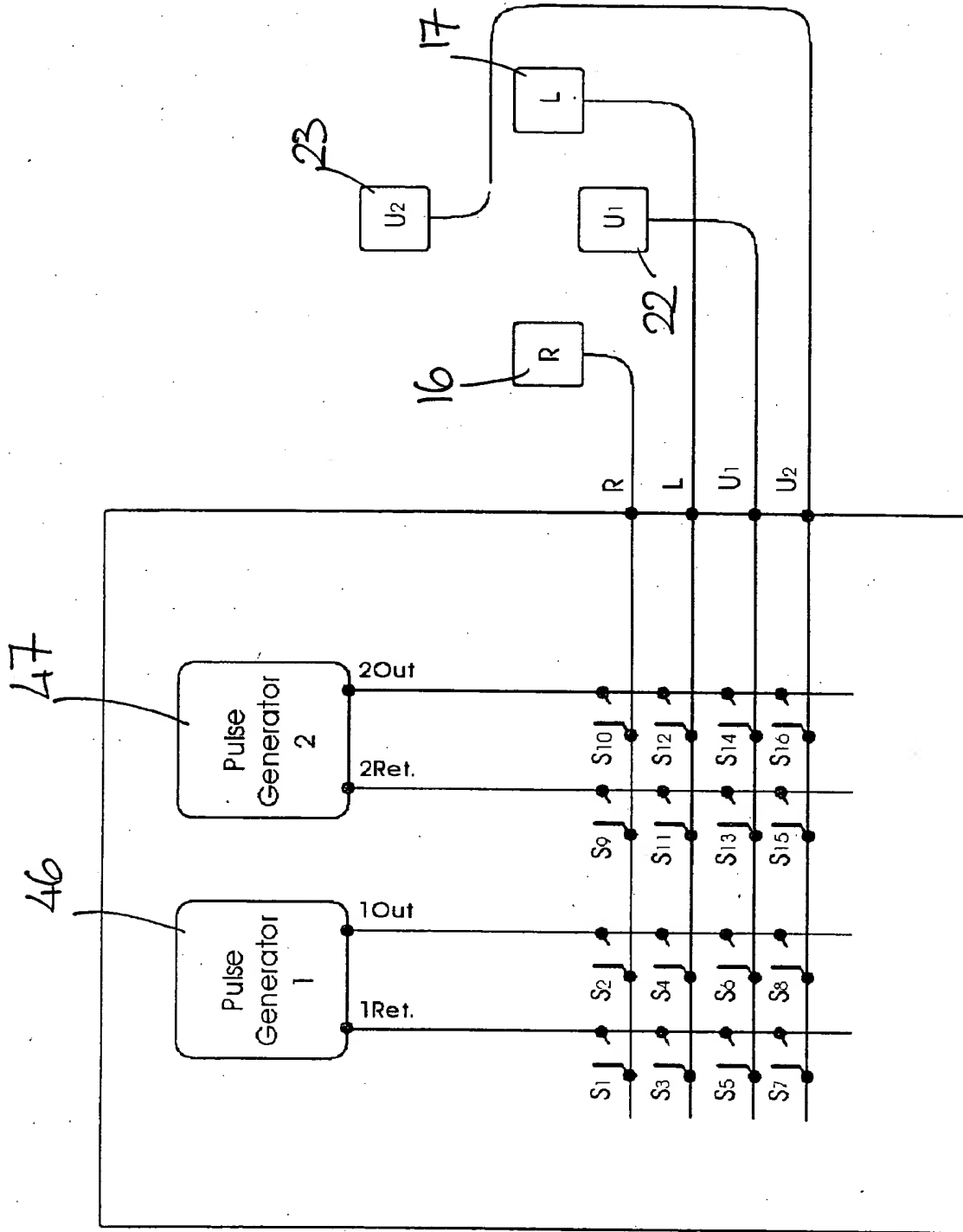


Fig. 25

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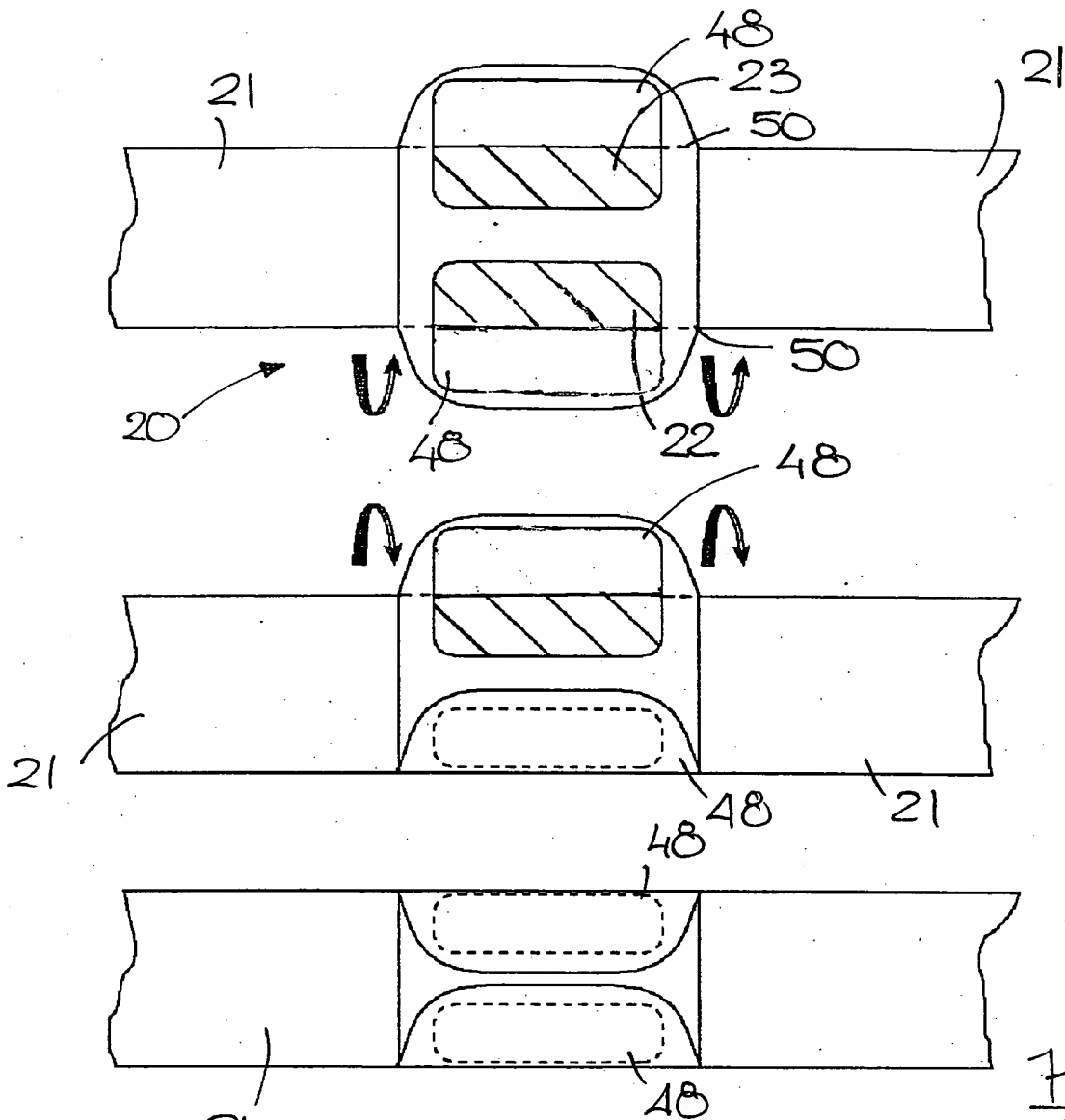
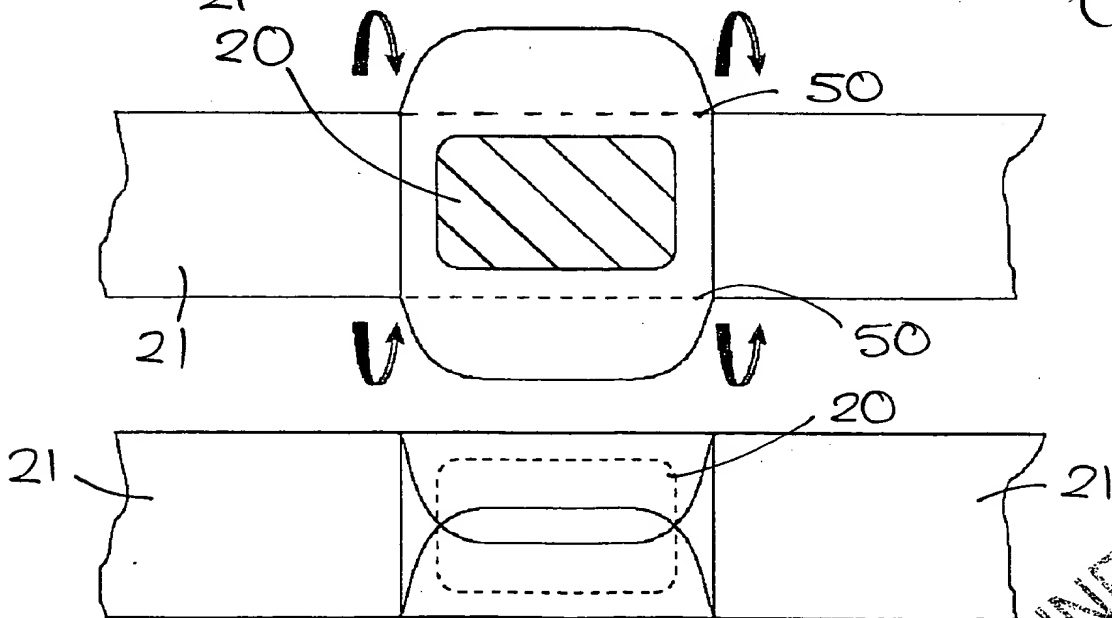


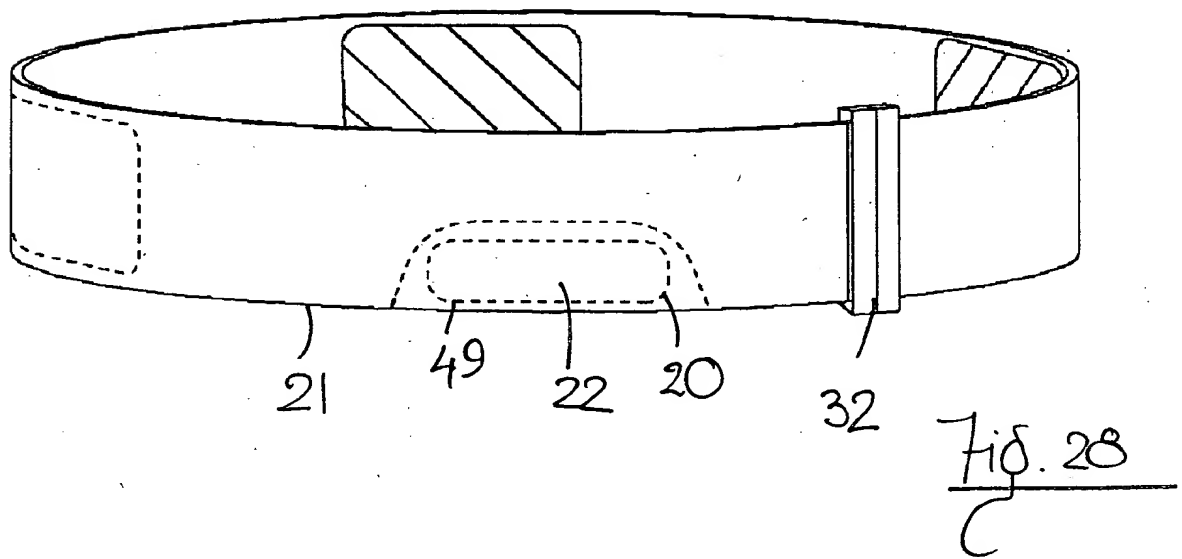
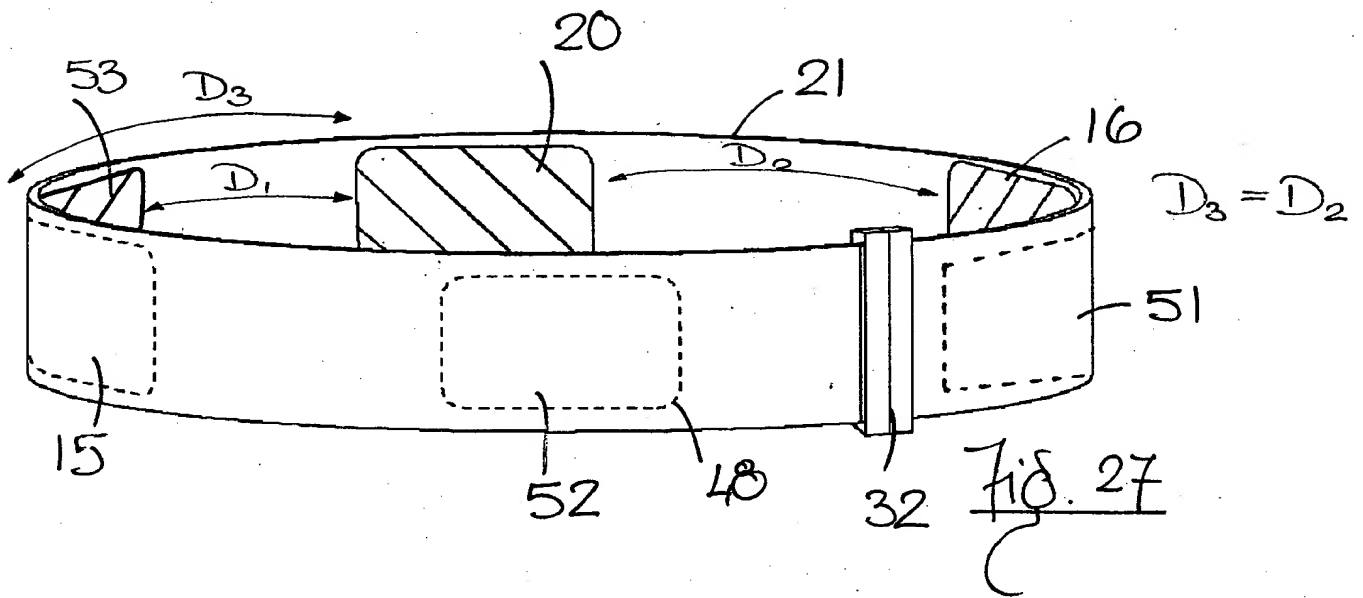
Fig. 26a



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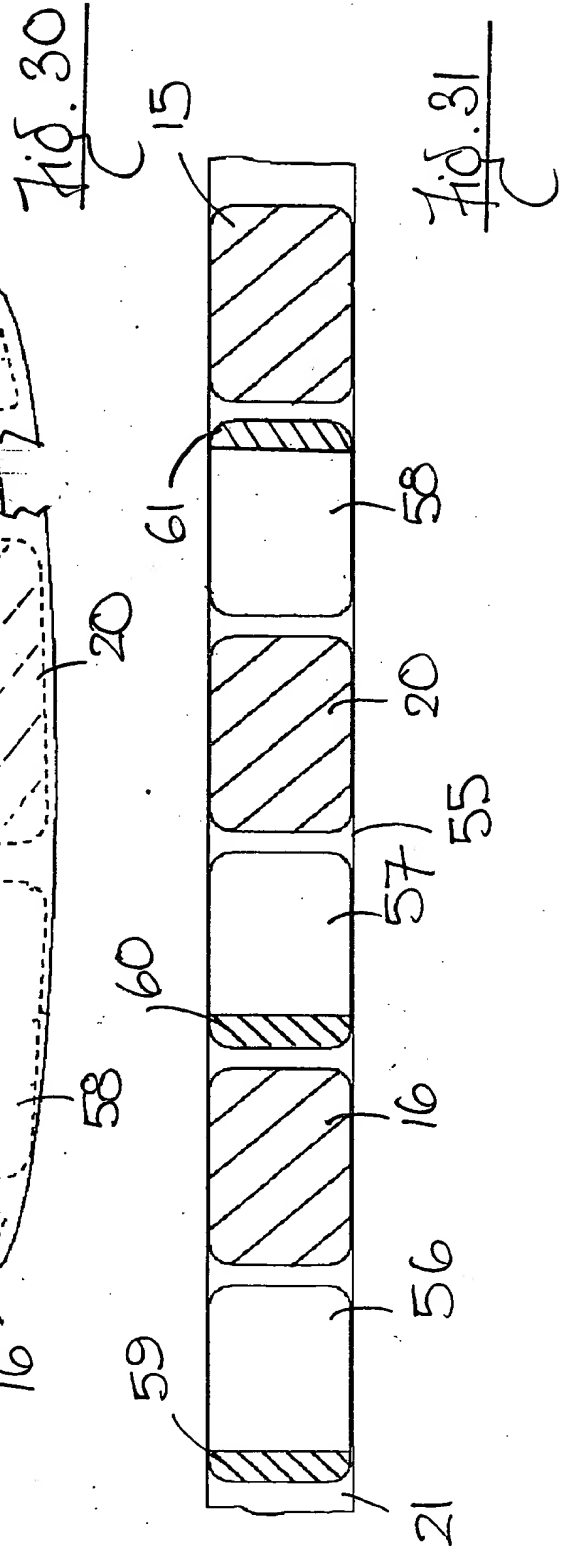
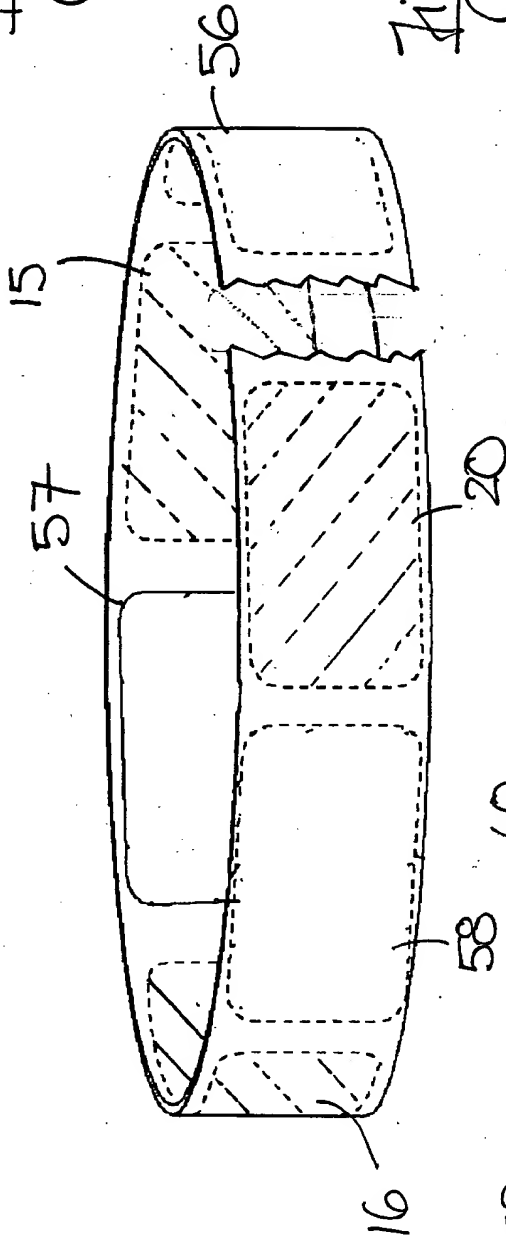
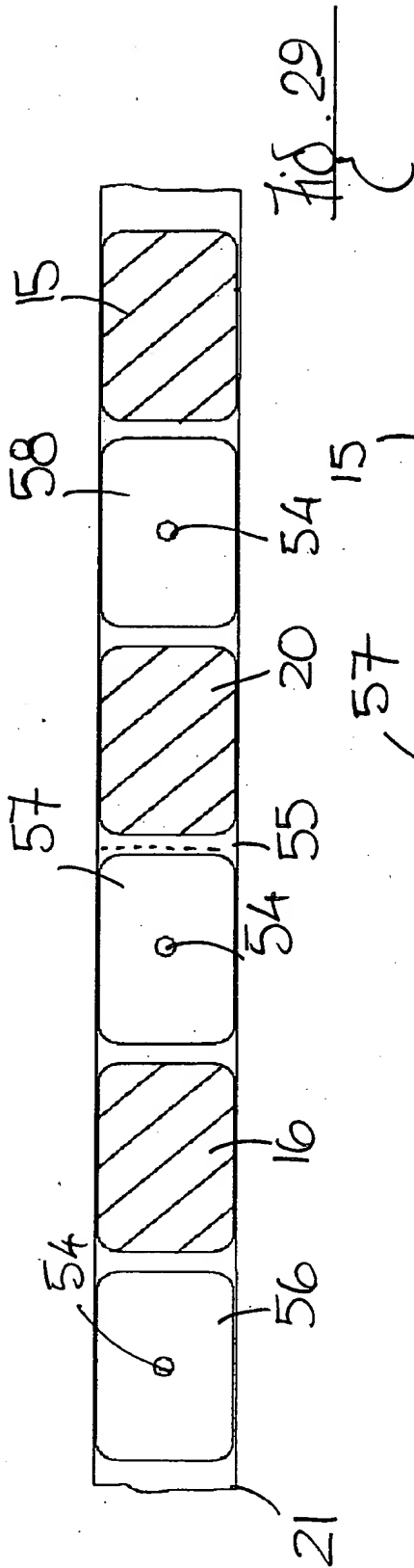
Fig. 26b

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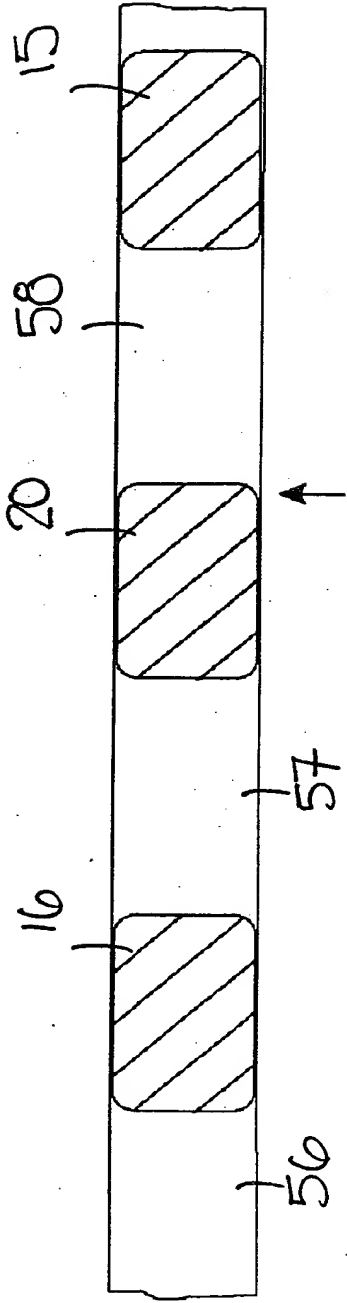


Fig. 32

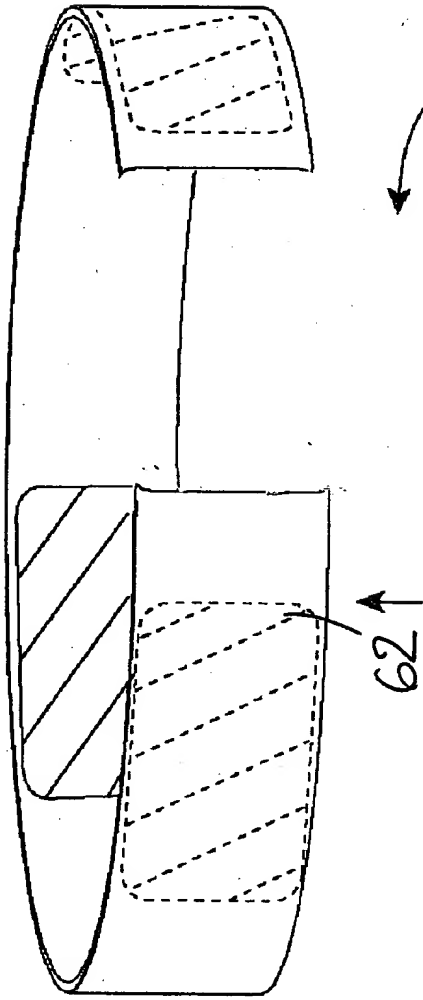


Fig. 33a

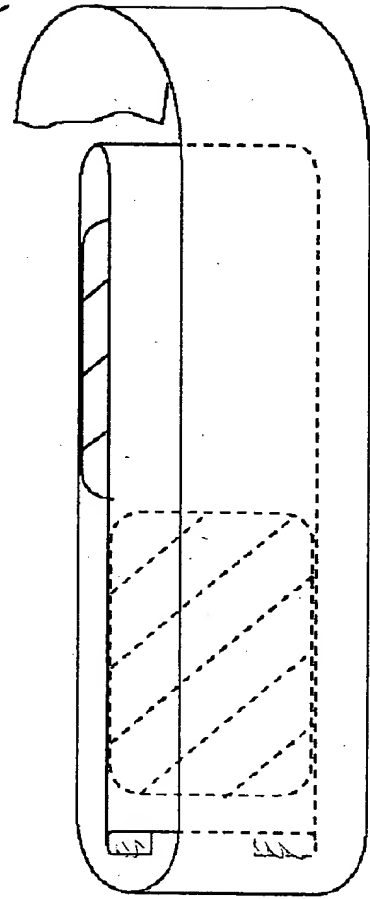


Fig. 33b

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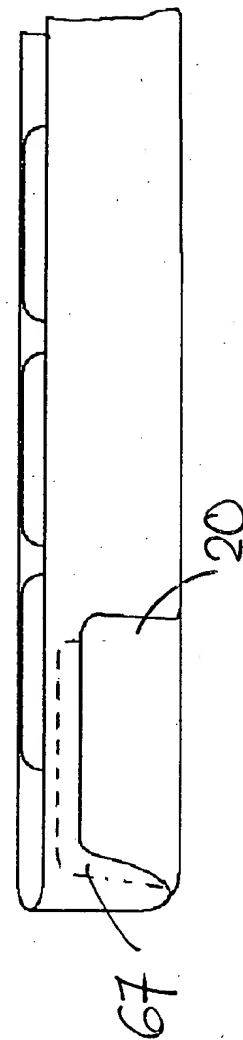
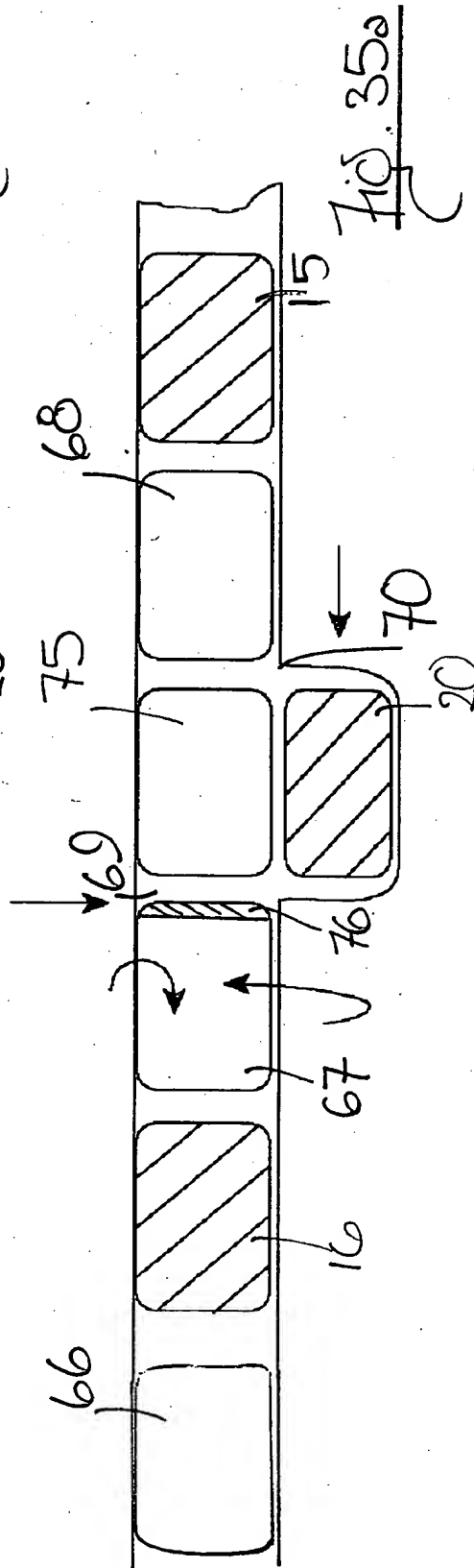
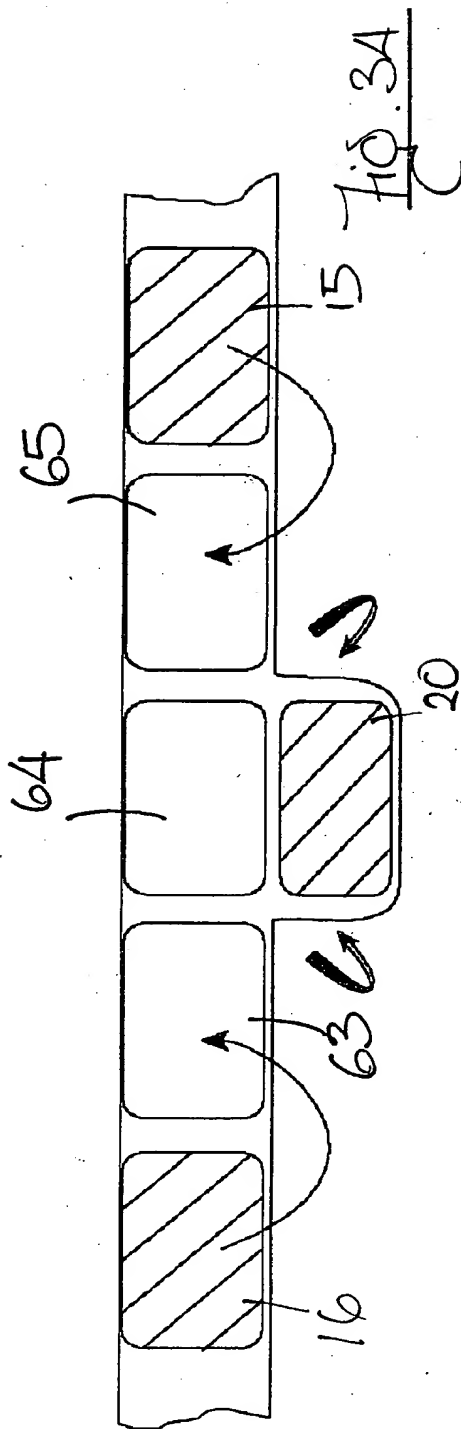


EXHIBIT I



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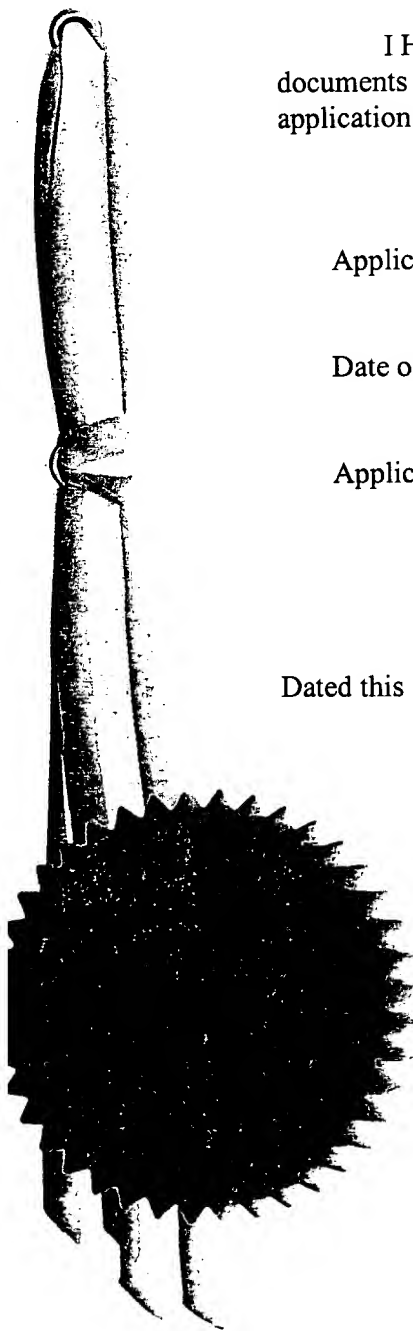
I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the PCT patent application:

Application No. PCT/IE2000/00004

Date of Filing 11 January 2000

Applicant BMR RESEARCH & DEVELOPMENT
LIMITED, Bunbeg, County Donegal, Ireland.

Dated this 22 day of February 2010.


Coleridge
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PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only	
International Application No.	PCT/IE 00 / 000004
International Filing Date	11 JAN 2000
Name of receiving Office and "PCT International Application"	
Applicant's or agent's file reference (if desired) (12 characters maximum)	

Box No. I TITLE OF INVENTION	
"An electrotherapy device and method"	
Box No. II APPLICANT	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
BMR RESEARCH & DEVELOPMENT LIMITED, Bunbeg, County Donegal, Ireland.	
<input type="checkbox"/> This person is also inventor. Telephone No. Facsimile No. Teleprinter No.	
State (that is, country) of nationality: IE	State (that is, country) of residence: IE
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
MINOGUE, Michael Conor, Croshua, Kinvara, County Galway, Ireland.	
This person is: <input type="checkbox"/> applicant only <input checked="" type="checkbox"/> applicant and inventor <input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)	
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<input checked="" type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE: OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
F.F. GORMAN & CO., 54 Merrion Square, Dublin 2, Ireland.	
Telephone No. 353-1-676 0363 Facsimile No. 353-1-676 1550 Teleprinter No.	
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CROWE, Louis Michael,
65 Beech Park Road,
Dublin 18,
Ireland.

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

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This person is:

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This person is:

- ☐ applicant only
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This person is:

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☐ applicant and inventor
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The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes: at least one must be marked):

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PCT/AE 00/000004

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
Item (1) January 11, 1999 (11.01.99)	599 0016	Ireland		
Item (2)				
Item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)

* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(iii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used.)	Request to use results of earlier search: reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):
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Box No. VIII CHECK LIST: LANGUAGE OF FILING

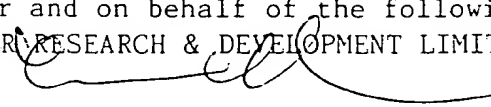
This international application contains the following number of sheets:	This international application is accompanied by the item(s) marked below:
request : 4	1. <input checked="" type="checkbox"/> fee calculation sheet
description (excluding sequence listing part) : 33	2. <input type="checkbox"/> separate signed power of attorney
claims : 17	3. <input type="checkbox"/> copy of general power of attorney; reference number, if any:
abstract : 1	4. <input type="checkbox"/> statement explaining lack of signature
drawings : 10	5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s):
sequence listing part of description :	6. <input type="checkbox"/> translation of international application into (language):
Total number of sheets : 65	7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material
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Figure of the drawings which should accompany the abstract: Figs. 5 to 10 Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

MICHAEL CONOR MINOGUE

 F.F.CORMAN & CO., Agent for the Applicant
 LOUIS MICHAEL CROWE

 F.F.CORMAN & CO., Agent for the Applicant

For and on behalf of the following:
 BMR RESEARCH & DEVELOPMENT LIMITED

 F.F.CORMAN & CO., Agent for the Applicant

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1. Date of actual receipt of the purported international application: 11 JAN 2002	2. Drawings: <input checked="" type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA EP	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.

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"An electrotherapy device and method"

The present invention relates to a device for attaching electrodes to a subject for stimulating abdominal muscles by electrotherapy, and the invention also relates to a device for stimulating abdominal muscles by electrotherapy. The invention further
5 relates to an electrotherapeutic method for stimulating abdominal muscles, and to a fastener for use in the device.

Electrotherapy is commonly used for stimulating abdominal muscles for improving
10 and toning the muscles, and for the relief of pain. Known electrotherapeutic methods and devices require that a pulsed signal be passed subcutaneously through the subject between a pair of electrodes which typically, are aligned with the muscle to be stimulated for defining a current path between the electrode which is co-linear with the direction of the muscle. In known electrotherapeutic devices and methods, it
15 is necessary to provide a relatively large number of electrode pairs for stimulating the more important abdominal muscles, for example, the central rectus abdominis muscle, and the transversalis and oblique muscles. Typically, one or two pairs of electrodes are required located on respective opposite sides of the umbilicus for stimulating the rectus abdominis muscle, and two obliquely located electrode pairs
20 are required towards the respective sides of the abdominal region for stimulating the transversalis and oblique muscles on the respective sides of the abdomen. Thus, in order to stimulate the rectus abdominis muscle, the transversalis and oblique muscles, three to four electrode pairs are required. This, leads to a number of disadvantages, in that firstly, unless extreme care is taken in locating the electrodes
25 on the abdomen of the subject some or all of the electrodes can readily easily be misaligned with the respective muscles or displaced therefrom, thus, leading to significant inefficiencies and indeed in extreme cases ineffectual treatment. Secondly, because of the high number of electrode pairs, a relatively complex signal generator is required for providing appropriately pulsed signals so that the pulsed
30 signals only travel between the respective pairs between which the pulsed signals are to travel subcutaneously in the subject. Thirdly, in many cases there is a danger of transthoracic current paths being defined by the electrodes, which in certain cases can lead to transthoracic currents within the subject, which in extreme cases may

cause cardiac arrhythmias. The possibility of misalignment of the electrode pairs further increases the risk of transthoracic currents being passed through the subject.

5 There is therefore a need for a device for attaching electrodes to a subject for stimulating abdominal muscles and in particular for stimulating the rectus abdominis, the transversalis and the oblique muscles, which overcomes these problems. There is also a need for an electrotherapeutic device and a method for stimulating abdominal muscles which overcomes these problems.

10 The present invention is directed towards providing such a device for attaching electrodes to a subject, such an electrotherapeutic device and method for stimulating abdominal muscles of a subject. The invention is also directed towards providing a fastener for use in the device.

15 According to the invention there is provided a device for attaching at least three electrodes to a subject for stimulating abdominal muscles of the subject, the device comprising an attachment means for extending around the torso of the subject, wherein a main locating means is provided on the attachment means for locating a central electrode of the at least three electrodes adjacent the umbilicus of the
20 subject, and two secondary locating means are provided on the attachment means disposed on respective opposite sides of the main locating means for locating two corresponding side electrodes of the at least three electrodes spaced apart from the central electrode in a general direction towards a corresponding one of the left and right mid-axillary lines of the torso intermediate the rib cage and corresponding left
25 and right iliac crests so that by applying at least one pulsed signal to the subject through the respective central and side electrodes abdominal muscles of the subject are stimulated.

In one embodiment of the invention the secondary locating means are disposed on
30 the attachment means for locating the respective side electrodes towards the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest. Preferably, the secondary locating means are disposed on

the attachment means for locating the respective side electrodes adjacent the corresponding mid-axillary line.

5 Ideally, the secondary locating means are disposed on the attachment means for locating the respective side electrodes adjacent the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest.

Preferably, the main locating means is disposed on the attachment means for locating the central electrode on the umbilicus and extending around the umbilicus.
10 Advantageously, the main locating means is disposed on the attachment means for locating the central electrode on the umbilicus and extending completely around the umbilicus.

15 In one embodiment of the invention the main locating means is disposed on the attachment means for locating the central electrode on the umbilicus, but with a greater area of the central electrode located below the umbilicus than above the umbilicus.

20 In another embodiment of the invention the main locating means is disposed on the attachment means for locating the central electrode adjacent but not on the umbilicus.

25 In a further embodiment of the invention the main locating means is disposed on the attachment means for locating the central electrode below the umbilicus.

In a still further embodiment of the invention the main locating means is disposed on the attachment means for locating the central electrode above the umbilicus.

30 In a further embodiment of the invention the main locating means is disposed on the attachment means for locating the central electrode both below and above the umbilicus.

In one embodiment of the invention a reference means is provided on the attachment means for locating the attachment means on the torso relative to an anatomical reference. Preferably, the reference means is provided for locating the attachment means circumferentially around the torso. Advantageously, the reference means is provided for locating the attachment means vertically along the torso.

In one embodiment of the invention the main locating means acts as the reference means for locating the attachment means relative to the anatomical reference provided by the umbilicus.

In another embodiment of the invention the main locating means comprises a first main locating means and a second main locating means for locating respective corresponding first and second central electrodes adjacent the umbilicus of the subject.

Advantageously, the first main locating means is provided for locating the first central electrode above the umbilicus, and the second main locating means is provided for locating the second central electrode below the umbilicus.

In another embodiment of the invention two sets of at least two secondary locating means are disposed on the respective opposite sides of the main locating means for facilitating selective location of the respective side electrodes for accommodating different girths of torso.

Advantageously, each set of secondary locating means comprises three secondary locating means.

In another embodiment of the invention portions of the attachment means on respective opposite sides of the main locating means between the main locating means and the corresponding secondary locating means are of resilient material for facilitating resilient stretching of the attachment means between the main and corresponding secondary locating means. Preferably, the attachment means is of a resilient material for facilitating stretching of the attachment means around the torso,

the resilient portions of the attachments means being of greater stretchability than that of the rest of the attachment means.

5 In one embodiment of the invention a main electrically conductive contact means is provided on the attachment means corresponding to each main locating means for receiving the at least one pulsed signal and for relaying the signal to the corresponding central electrode. Preferably, each main contact means is located within the corresponding main locating means.

10 In another embodiment of the invention two secondary electrically conductive contact means are provided on the attachment means for receiving the at least one pulsed signal and for relaying the signal to the respective corresponding side electrodes. Advantageously, each secondary contact means is located adjacent the corresponding secondary locating means or the corresponding set of secondary
15 locating means.

In another embodiment of the invention each secondary contact means is located adjacent the corresponding set of secondary locating means so that irrespective of which secondary locating means is selected for locating the corresponding side
20 electrode the side electrode is in electrically conductive engagement with the secondary contact means.

Advantageously, each main and secondary locating means is provided by a visually perceptive locating means. Preferably, each main and secondary locating means is
25 formed by a corresponding locating mark on the attachment means.

Ideally, each locating mark defines an outline of a part of the periphery of the corresponding electrode corresponding to the locating means.

30 In one embodiment of the invention each locating means is adapted for locating a patch type electrode.

In another embodiment of the invention the device comprises the at least three electrodes. Preferably, each electrode is a patch type electrode.

5 In one embodiment of the invention each side electrode is sized to cover at least a portion of the corresponding lower thoracic nerves and the corresponding first and second lumbar nerves.

10 In another embodiment of the invention each central electrode is sized to extend substantially across the rectus abdominus muscle.

Advantageously, each electrode defines an area of contact over which the electrode makes direct electrical contact with the subject, the area of contact of each side electrode being such as not to exceed the area of contact of the or both central electrodes. Preferably, the area of contact of each side electrode does not exceed
15 one third of the area of contact of the or both central electrodes.

In one embodiment of the invention each side electrode is of width in a circumferential direction relative to the torso of the subject in the range of 50mm to 150mm, and is of length in a vertical direction relative to the torso of the subject in
20 the range of 80mm to 120mm.

In one embodiment of the invention a first electrically conductive coating is provided on one side of each electrode for electrically connecting the electrode to the corresponding contact means. Advantageously, the first coating is a gel type coating
25 containing an electrolyte solution for enhancing electrical contact between the electrode and the corresponding contact means.

In another embodiment of the invention a second electrically conductive coating is provided on the other side of each electrode for electrically connecting the patch
30 electrode and the torso of the subject. Preferably, the second coating is a gel type coating.

In one embodiment of the invention the second coating is an adhesive coating.

In another embodiment of the invention the first coating is an adhesive coating.

Advantageously, the bond strength of the first coating to the attachment means is
5 greater than the bond strength of the second coating to the torso for facilitating
removal of the attachment means and the electrodes located thereon from the torso
of the subject.

Preferably, the electrodes are pre-coated with the respective first and second
10 adhesive coatings.

In one embodiment of the invention a receiving means is provided in the attachment
means for receiving a signal generating means for generating the at least one pulsed
signal.

15 Preferably, a main electrical connecting means extends between the receiving
means and each main contact means for relaying the at least one pulsed signal from
the signal generating means to the corresponding main contact means.

20 Advantageously, a secondary electrical connecting means extends between the
receiving means and each secondary contact means for relaying the at least one
pulsed signal from the signal generating means to the corresponding secondary
contact means.

25 Ideally, each electrical connecting means is located within the attachment means.

In one embodiment of the invention the receiving means is a releasable receiving
means for releasably receiving the signal generating means.

30 Advantageously, the receiving means receives the signal generating means with a
snap fit action.

In one embodiment of the invention the signal generating means for generating the at least one pulsed signal is provided in the receiving means.

5 In one embodiment of the invention a means is provided for selectively selecting at least one pair of electrodes from the at least three electrodes through which the at least one pulsed signal is applied to the subject.

10 In another embodiment of the invention the at least one pulsed signal is applied simultaneously to each of the selected pairs of electrodes. Alternatively, the at last one pulsed signal is applied sequentially to each of the selected pairs of electrodes.

15 In one embodiment of the invention one of the selected pairs of the electrodes comprises one side electrode and the central electrode, and another selected pair of the electrodes comprises the other side electrode and the central electrode.

In another embodiment of the invention one of the selected pairs of electrodes comprises the two side electrodes.

20 In another embodiment of the invention one of the selected pairs of electrodes comprises one of the side electrodes and one of the first and second central electrodes, and another of the selected pairs of electrodes comprises the other of the side electrodes and the other of the first and second central electrodes.

25 In a further embodiment of the invention one of the selected pairs of electrodes comprises the first and second central electrodes which act as one single electrode and one of the side electrodes, and another of the selected pairs of electrodes comprises the first and second central electrodes which act as one single electrode and the other side electrode.

30 In a still further embodiment of the invention one of the selected pairs of electrodes comprises the first and second central electrodes.

In one embodiment of the invention the pulsed signals generated by the signal generating means for applying to the respective pairs of electrodes may be the same or different.

5 In one embodiment of the invention each pulsed signal comprises a plurality of pulses at intervals in the range of 5 milliseconds to 1000 milliseconds. Preferably, each pulsed signal comprises a plurality of pulses at intervals in the range of 20 milliseconds to 40 milliseconds.

10 Advantageously, each pulsed signal comprises a plurality of pulses at intervals of approximately 30 milliseconds \pm 20%. Preferably, the interval between pulses of each pulsed signal is adjustable.

In another embodiment of the invention each pulsed signal comprises pulses of
15 duration in the range of 10 microseconds to 200000 microseconds. Advantageously, each pulsed signal comprises pulses of duration in the range of 50 microseconds to 1000 microseconds.

Preferably, each pulsed signal comprises pulses of duration in the range of 100
20 microseconds to 500 microseconds. Ideally, each pulsed signal comprises pulses of duration of approximately 300 milliseconds \pm 20%. Preferably, the duration of each pulsed signal is adjustable.

In another embodiment of the invention each pulsed signal comprises a plurality of
25 pulses of magnitude in the range of 0mA to 100mA. Preferably, the magnitude of each pulse of each pulsed signal is adjustable.

In one embodiment of the invention the attachment means comprises a belt.

30 In another embodiment of the invention a securing means is provided on the belt for securing the belt around the torso of the subject.

In a further embodiment of the invention a main fastening means is provided corresponding to each main locating means for fastening a corresponding central electrode to the attachment means adjacent the corresponding main locating means.

- 5 In a still further embodiment of the invention two secondary fastening means are provided in the attachment means for fastening the respective side electrodes to the attachment means adjacent the corresponding selected secondary locating means.

10 In one embodiment of the invention each fastening means comprises a stud fastener.

In another embodiment of the invention each stud fastener comprises a female part and a male part, the female part being secured to the attachment means.

- 15 In a further embodiment of the invention each stud fastener is electrically conductive so that the female part of the stud fasteners form the corresponding contact means.

20 Preferably, an exposed surface of the female part of each stud fastener is of electrically insulating material.

Advantageously, the exposed surface of each female part of each stud faster is coated with an electrically insulating coating.

- 25 Additionally, the invention provides a stud fastener for use in the device according to the invention, the stud fastener comprises a male part for attaching to a corresponding electrode, and a female part for attaching to the attachment means.

In one embodiment of the invention the male and female parts of the stud fastener engage each other with electrically conductive engagement.

- 30 In another embodiment of the invention an exposed external surface of the female part of the stud fastener which abuts the male part of the stud fastener is of electrically insulating material.

In a further embodiment of the invention the electrically insulating material is provided by an electrically insulated coating on the exposed abutting surface.

- 5 The invention further provides a method for stimulating abdominal muscles of a subject, the method comprising passing at least one pulsed signal subcutaneously through the subject between selected electrodes of at least three electrodes, one of the at least three electrodes being a central electrode located adjacent the umbilicus of the subject, and the other two electrodes being side electrodes located on the
10 subject spaced apart from the central electrode on respective sides thereof in a general direction towards a corresponding one of the left and right mid-axillary lines of the torso intermediate the rib cage and corresponding left and right iliac crests.

- In one embodiment of the invention each side electrode is located towards the mid-point of the corresponding mid-axillary line between the rib cage and the
15 corresponding iliac crest. Preferably, each side electrode is located adjacent the corresponding mid-axillary line. Ideally, each side electrode is located adjacent the mid-point of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest.

- 20 Preferably, the central electrode is located on the umbilicus and extends around the umbilicus. Advantageously, the central electrode is located on the umbilicus and extends completely around the umbilicus.

- 25 In one embodiment of the invention the central electrode is located on the umbilicus, but with a greater area of the central electrode located below the umbilicus than above the umbilicus.

- In another embodiment of the invention the central electrode is located adjacent but
30 not on the umbilicus.

In a further embodiment of the invention the central electrode is located below the umbilicus.

In a still further embodiment of the invention the central electrode is located above the umbilicus.

- 5 In another embodiment of the invention the central electrode is located both below and above the umbilicus.

In a still further embodiment of the invention the central electrode is provided by two electrodes, namely, a first central electrode and a second central electrode, both of
10 which are located adjacent the umbilicus. Preferably, the first central electrode is located above the umbilicus and the second central electrode is located below the umbilicus.

- 15 In one embodiment of the invention the at least one pulsed signal is applied to the subject so that the signal passes subcutaneously through the subject between at least one selected pair of the at least three electrodes.

In one embodiment of the invention the at least one pulsed signal is applied simultaneously to each of the selected pairs of electrodes. Alternatively, the at last
20 one pulsed signal is applied sequentially to each of the selected pairs of electrodes.

In one embodiment of the invention one of the selected pairs of electrodes comprises one side electrode and the central electrode, and another selected pair of electrodes comprises the other side electrode and the central electrode.

25

In another embodiment of the invention one of the selected pairs of electrodes comprises the two side electrodes.

30 In a further embodiment of the invention one of the selected pairs of electrodes comprises one of the side electrodes and one of the first and second central electrodes, and another of the selected pairs comprises the other of the side electrodes and the other of the first and second central electrodes.

In a still further embodiment of the invention one of the selected pairs of electrodes comprises the first and second central electrodes which act as one single electrode and one of the side electrodes, and another of the selected pairs of electrodes comprises the first and second central electrodes which act as one single electrode and the other side electrode.

In a further embodiment of the invention one of the selected pairs of electrodes comprises the first and second central electrodes.

In one embodiment of the invention the pulsed signals applied to the respective pairs of electrodes may be the same or different.

In one embodiment of the invention each pulsed signal comprises a plurality of pulses at intervals in the range of 5 milliseconds to 1000 milliseconds. Preferably, each pulsed signal comprises a plurality of pulses at intervals in the range of 20 milliseconds to 40 milliseconds. Advantageously, each pulsed signal comprises a plurality of pulses at intervals of approximately 30 milliseconds \pm 20%.

Ideally, the interval between pulses of each pulsed signal is adjustable.

In one embodiment of the invention each pulsed signal comprises pulses of duration in the range of 10 microseconds to 200000 microseconds. Preferably, each pulsed signal comprises pulses of duration in the range of 50 microseconds to 1000 microseconds:

Advantageously, each pulsed signal comprises pulses of duration in the range of 100 microseconds to 500 microseconds. Ideally, each pulsed signal comprises pulses of duration of approximately 300 milliseconds \pm 20%. Preferably, the duration of each pulsed signal is adjustable.

In another embodiment of the invention each pulsed signal comprises a plurality of pulses of magnitude in the range of 0mA to 100mA. Preferably, the magnitude of each pulse of each pulsed signal is adjustable.

Further the invention provides an electrotherapeutic device for stimulating muscles of a muscle group of a subject, the device comprising a plurality of electrodes for placing on the subject for applying at least one pulsed signal to the subject for stimulating the muscles, a signal generating means for generating the at least one pulsed signal, and a selecting means for selectively selecting the electrodes in electrode pairs and for selectively applying the at least one pulsed signal to the selected electrode pairs for selective stimulation of the muscles of the muscle group.

10 In one embodiment of the invention the selecting means comprises a switching means for selectively switching the at least one pulsed signal from the signal generating means to the electrodes.

Additionally, the invention provides a method for stimulating muscles of a muscle group of a subject, the method comprising passing at least one pulsed signal subcutaneously through the subject between selected electrodes of at least three electrodes, wherein the electrodes are selectively selected in electrode pairs for selectively stimulating selected muscles of the muscle group.

20 In one embodiment of the invention the electrode pairs are sequentially selected from the electrodes. Alternatively, the electrode pairs are simultaneously selected from the electrodes.

The advantages of the invention are many. An important advantage of the invention is that it permits relatively accurate placement and alignment of the electrodes on the subject. A particularly important advantage of the invention results from the fact that the device according to the invention permits relatively accurate placement of the electrodes on the subject, and because of this, it has been found that with only three electrodes the device according to the invention provides adequate stimulation to the abdominal muscles, and in particular, to the rectus abdominis and the transversalis and oblique muscles, particularly, for the purpose of toning the muscles. It has been surprisingly found that by locating the central electrode adjacent the umbilicus, and the respective side electrodes towards the corresponding mid-axillary lines to the

respective left and right sides of the central electrode good stimulation of the abdominal muscles is achieved. However, it has been found that the closer the side electrodes are located to the corresponding left and right mid-axillary lines the better will be the stimulation. Indeed, it has been found that optimum stimulation is

5 achieved by locating the respective side electrodes on corresponding lines extending from the umbilicus to the mid-point on the corresponding left and right mid-axillary lines between the rib cage and the corresponding iliac crest. In general, it has been found the maximum stimulation of the rectus abdominis, the transversalis and the oblique muscles is achieved when the side electrodes are located on the

10 corresponding mid-axillary line substantially midway between the rib cage and the iliac crest. A further advantage of the invention is achieved where first and second central electrodes are provided, one above and the other below the umbilicus where it has been found that even greater stimulation of the abdominal muscles is achieved, and in particular, stimulation of the rectus abdominis, the transversalis and

15 the oblique muscles.

By providing the side electrodes adjacent the mid-axillary line or spaced part from the central electrode towards the mid-axillary line, but relatively close to the mid-axillary line the side electrodes apply the pulsed signal or signals to nerve trunks

20 rather than nerve branches which spread out from the nerve trunks. The electrical signals being applied to the nerve trunks, thus spread out through the nerve branches from the nerve trunks, and are thus effective in stimulating a significantly greater area of the muscles of the abdomen than if the electrodes were placed over nerve branches as has been the case heretofore. Additionally by placing the central

25 electrode over or adjacent the umbilicus, and the side electrodes adjacent or relatively close to the mid-axillary line, the spacing between the central and side electrodes is such as to cause the pulsed signal or signals to travel deeper through the subject beneath the fatty tissue. This, thus, results in the pulsed signal or signals being targeted at the deeper muscle controlling nerves, thus providing more efficient

30 stimulation of the muscles. Placing the electrodes relatively closely together, as has been the case heretofore, tends to cause the pulsed signal or signals to pass relatively near the surface of the skin, thus having little affect on the deeper muscle controlling nerves. Indeed, a further advantage of spacing the electrodes apart

according to the invention is that the effect of subcutaneous currents on the touch and pain nerves is minimised, thereby minimising discomfort to the subject.

Additionally, by providing the side electrodes of size to extend across the lower thoracic nerves and the first lumbar nerves adjacent the mid-axillary line further

5 efficiency is achieved by virtue of the fact that the pulsed signal or signals is applied to the nerve trunks of these nerves. A further advantage of providing the electrodes of reasonable size is that the current density of the pulsed signal or signals passing through the electrodes, and in turn into the subject is minimised, thus, further minimising discomfort resulting from the effect of the subcutaneous current on the
10 touch and pain nerves. Indeed, by providing the electrodes of reasonable size, a higher current may also be applied through the electrodes if such should be desired with minimum discomfort to the subject.

A further advantage of the invention is that it is virtually impossible to incorrectly
15 attach or misapply the electrodes to the subject, and furthermore, there is virtually no danger of the pulsed signals being applied to the wrong electrodes, since the attachment means is pre-wired with the main and secondary connecting means.

A further advantage of the invention is achieved when provision is made for
20 selectively selecting the electrodes into electrode pairs, in that individual muscles of muscle groups may be selectively stimulated, and additionally, if desired different pulsed signals may be applied to different selected electrode pairs.

The invention will be more clearly understood from the following description of some
25 preferred embodiments thereof which are given by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a front elevational view of a torso of a subject,

30 Fig. 2 is a front plan view of a device according to the invention for stimulating abdominal muscles,

Fig. 3 is a rear plan view of the device of Fig. 2,

Fig. 4 is an exploded perspective view of a detail of the device of Fig. 2,

Fig. 5 is a rear plan view of a portion of the device of Fig. 2 illustrating
5 electrode pads positioned on the device,

Fig. 6 is a cut-away rear plan view of another portion of the device of Fig. 2,

Figs. 7 and 8 are perspective views of respective electrodes of the device of
10 Fig. 2,

Fig. 9 is a transverse cross-sectional view of the electrode of Fig. 7 on the line
IX-IX of Fig. 7,

Fig. 10 is a front elevational view of a torso of a subject illustrating the device
15 of Fig. 2 in use,

Fig. 11 is a front elevational view of the torso of the subject of Fig. 10
20 illustrating the correct positioning of the electrodes of the device of Fig. 2,

Fig. 12 is a side elevational view of the torso of the subject of Fig. 10 also
illustrating the correct positioning of the electrodes of the device of Fig. 2,

Fig. 13 is a block representation of a circuit of the device of Fig. 2,

Fig. 14 is a graphical representation of pulsed signals generated by the device
25 of Fig. 2,

Fig. 15 is a block representation of an alternative circuit arrangement of the
30 device of Fig. 2,

Fig. 16 is a graphical representation of pulsed signals generated by the device
of Fig. 2 in the configuration of Fig. 15,

Fig. 17 is a block representation of an alternative circuit arrangement of the device of Fig. 2,

5 Fig. 18 is a graphical representation of pulsed signals generated by the device of Fig. 2 in the configuration of Fig. 17,

Fig. 19 is a rear plan view of a device according to another embodiment of the invention for stimulating abdominal muscles,

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Fig. 20 is a front elevational view of a torso of a subject illustrating the device of Fig. 19 in use,

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Fig. 21 is a front elevational view of the torso of the subject of Fig. 20 illustrating correct positioning of electrodes of the device of Fig. 19,

Figs. 22 to 24 are block representations of alternative configurations of the circuit of the device of Fig. 19,

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Fig. 25 is a diagrammatic representation of subcutaneous current paths which may be developed in the subject using the device of Fig. 19,

Fig. 26 is a block representation of one circuit configuration of the device of Fig. 19,

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Fig. 27 is a block representation of an alternative circuit configuration of the device of Fig. 19,

30

Fig. 28 is a rear plan view of a device according to another embodiment of the invention for stimulating abdominal muscles,

Fig. 29 is an exploded transverse cross-sectional view of a detail of the device of Fig. 28, and

Fig. 30 is a perspective view of a portion of a detail of the device of Fig. 28.

Referring to the drawings and initially to Figs. 1 to 18 there is illustrated an
5 electrotherapeutic device according to the invention indicated generally by the
reference numeral 1 for stimulating abdominal muscles of a subject, and in
particular, for stimulating the rectus abdominis, the transversalis and oblique
muscles of the abdomen of the subject for toning of the muscles. Before describing
the device 1 the position of the muscles in the abdominal wall of the subject will first
10 be described with reference to Fig. 1.

Referring now in particular to Fig. 1 a torso 3 of a subject is illustrated. The abdomen
5 of the subject is located between the rib cage 6 and the pelvis 7 and between the
left and right iliac crests 8 and 9, respectively on the respective left and right sides
10 and 11, respectively of the subject. The umbilicus 12 is located centrally in the
abdomen 5. The left and right mid-axillary lines 13 and 14 extend between the left
and right iliac crests and the rib cage 6 on the left and right sides 10 and 11 of the
torso 3. Rectus abdominis muscles which are indicated by the reference numeral 15
15 extend substantially longitudinally from a position below the rib cage 6 to a position
above the pelvis, while the transversalis muscles which are indicated by the
reference numeral 16 extend transversely across the abdomen between the left and
right sides 10 and 11 thereof, while the oblique muscles indicated by the reference
17 extend obliquely between respective positions below the rib cage 6 to one side
thereof and a central position adjacent the pelvis 7.

25 In known electrotherapeutic devices and methods, in order to stimulate these three
muscles, namely, the rectus abdominis muscles 15, the transversalis muscles 16
and the oblique muscles 17 pulsed signals are applied to the abdomen of the subject
through four electrode pairs 20a and 20b, 21a and 21b, 22a and 22b, 23a and 23b
30 arranged as illustrated in Fig. 1. The electrode pairs 20a and 20b and 21a and 21b
stimulate the rectus abdominis muscles 15, while the electrode pairs 22 and 23 a
and b stimulate the transversalis muscles and oblique muscles for toning thereof.

Referring now in particular to Figs. 2 to 12 the device 1 comprises an attachment means, namely, a belt 25 for extending around the torso 3 of the subject for locating and retaining three electrodes, which in this embodiment of the invention are patch electrodes, namely, a central electrode 26 and a pair of side electrodes 27 adjacent the abdomen 5 for applying one or more pulsed signals generated by a signal generating means, namely, a signal generator 28 which is releasably located in the belt 25 as will be described below. A main locating means and two sets of secondary locating means provided respectively by main and secondary locating marks 29 and 30, respectively, are provided on an inner side 34 of the belt 25 for locating the central electrode 26 and the side electrodes 27, respectively on the belt 25.

The main locating marks 29 define two opposite peripheral sides of the central electrode 26 for defining a main locating area 31 for receiving and locating the central electrode 26 for accurately locating the central electrode 26 on the belt 25 to in use lie centrally over the umbilicus 12. In this embodiment of the invention each set of secondary locating marks 30a, 30b and 30c define three respective secondary locating areas 32a, 32b and 32c at which the respective side electrodes 27 may be selectively attached to the belt 25 so that in use the side electrodes preferably lie centrally over the corresponding one of the left and right mid-axillary lines 13 and 14 of the subject and on a mid-point which is substantially midway between the rib cage 6 and the corresponding one of the left and right iliac crests 8 and 9. Although in practice while it is desirable that the side electrodes 27 should line on the corresponding mid-axillary lines, it has been found that, in general, adequate stimulation of the muscles is achieved if the side electrodes 27 are located on the belt 25 to lie on respective lines extending from the umbilicus to the mid-point of the corresponding mid-axillary lines and towards the mid-axillary lines. In this embodiment of the invention the secondary locating marks 30a, 30b and 30c define a periphery 33 of one end of the corresponding side electrode 27 for indicating the three secondary locating areas 32a, 32b and 32c at which the side electrodes 27 may be located on the belt 25 for accommodating torsos of different girth about the waist.

The main locating area 31 and the secondary locating areas 32a, 32b and 32c are arranged on the belt 25 so that when the central electrode 26 is located in the main locating area 31, and the side electrodes 27 are located in the appropriate one of the secondary locating areas 32a, 32b or 32c, and when the belt 25 is secured around
5 the torso 3 with the central electrode 26 located centrally over the umbilicus 12 the respective side electrodes 27 are located over the left and right mid-axillary lines 13 and 14, respectively, between the rib cage 6 and the left and right iliac crests 8 and 9, or relatively close to the mid-axillary lines.

10 A securing means, in this embodiment of the invention provided by hooks and eyes of the type typically sold under the Trade Mark VELCRO is provided at the respective ends 35 and 36 of the belt 25, a band of hooks 38 of the hooks and eyes being provided on the inner side 34 at the end 35, while bands of eyes 39 of the hooks and eyes are provided on the outer side 40 at the end 36 of the belt 25. In this
15 embodiment of the invention four bands of eyes 39 are provided at spaced apart intervals for facilitating securing of the belt 25 to torsos 3 of different girth about the waist.

An electrically conductive main contact means, namely, an electrically conductive
20 main contact 45 is located on the belt 25 centrally in the main locating area 31 for applying one or more pulsed signals generated by the signal generator 28 to the central electrode 26. A pair of secondary contact means provided by electrically connective secondary contacts 46 are located in the respective sets of secondary locating areas 32 for applying signals generated by the signal generator 28 to the
25 respective side electrodes 27. Each secondary contact 46 is located in the sets of secondary locating areas 32 in such a way that irrespective of which of the secondary locating areas 32 is selected for receiving the side electrode 27 the side electrode 27 is always in contact with the corresponding secondary contact 46.

30 A reference means for locating the belt 25 relative to an anatomical reference, namely, the umbilicus in this embodiment of the invention is provided by the main locating area 31, and in turn the central electrode 26 for locating the belt 25 on the torso 3. The central electrode 26 when it is centrally located in the main locating area

31 is provided in a position so that when the belt 25 is secured to the torso 3 with the central electrode 26 centrally located on the umbilicus 12 the belt 25 is centrally located circumferentially and vertically on the torso 3. Thus, when the belt 25 is tightly secured around the torso 3 the side electrodes 27 are relatively accurately
5 located over or relatively close to the mid-axillary lines 13 and 14 centrally between the rib cage 6 and the respective left and right iliac crests 8 and 9.

In order that the belt 25, and in turn the central and side electrodes 26 and 27 are tightly secured to the subject, and also to further accommodate varying girths of
10 torso 3, the belt 25 is of a resilient elasticated material for facilitating stretching of the belt 25 between the respective ends 35 and 36. However, to further facilitate in accommodating torsos 3 of different girths, portions 47 between broken lines 48, see Fig. 3 of the belt 25 on respective opposite sides of the main locating area 29 and between the nearest secondary locating areas 32a are more resilient than the rest of
15 the belt 25 for accommodating extra stretchability of the belt 25 in the resilient portions 47. This, further facilitates in aligning the side electrodes 27 with the respective left and right mid-axillary lines 13 and 14.

The belt 25 comprises a pair of outer layers 49 of stretchable textile material, and an
20 inner layer 50 of stretchable foam material which are secured together by an edging braid 51 extending on respective opposite sides of the belt 25 and stitched to the outer layers 49 and the inner layer 50. The braid 51 is also of a stretchable material, and the stitching of the braid 51 to the outer and inner layers 49 and 50, respectively is arranged for providing greater stretchability in the resilient portions 47 than in the
25 rest of the belt 25.

A receiving means in this embodiment of the invention provided by a receiving bracket 54 of plastics material is secured to the outer side 40 of the belt 25 for releasably securing the signal generator 28 to the belt 25. Guide tracks 55 in the
30 receiving bracket 54 engage corresponding guide grooves 56 on the signal generator 28 with a snap fit action for releasably and securely retaining the signal generator 28 in the receiving bracket 54. A three contact jack plug 57 located in the receiving bracket 54 engages a corresponding three contact jack socket 58 in the

signal generator 28 for connecting the signal generator 28 to the central and side electrodes 26 and 27.

5 Main and secondary connecting means, namely, main and secondary cables 59 and 60, respectively, extending from the jack plug 57 are respectively connected to the main contact 45 and the secondary contacts 46. The main and secondary cables 59 and 60 are located between the outer layers 49 of the belt 25, and the secondary cables 60 are provided in concertina shape for facilitating expansion of the resilient portions 47 of the belt 25. Control buttons 62 are provided on the signal generator 28
10 for operating corresponding control switches within the signal generator 28 for controlling the signals generated by the signal generator 28 as will be described below.

Turning now to the central and side electrodes 26 and 27, and referring in particular
15 to Figs. 7 to 9 the electrodes 26 and 27 are formed from electrically conductive foil 65. A first electrically conductive means comprising a first electrically conductive adhesive gel coating 67 is provided on one side 66 of the foil 65 for securing the respective central and side electrodes 26 and 27 to the belt 25 and for providing electrical continuity between the foil 65 of the electrodes 26 and 27 and the
20 corresponding main or secondary contacts 45 and 46, respectively. A second electrically conductive means, namely, a secondary electrically conductive adhesive gel coating 68 is provided on the other side 69 of the foil 65 for adhering the electrodes 26 and 27 to the skin of the subject and for providing good electrical continuity between the respective electrodes 26 and 27 and the skin of the subject.
25 In this embodiment of the invention in order to further enhance electrical continuity between the foil 65 of the electrodes 26 and 27 and the corresponding main and secondary contacts 45 and 46 the first adhesive coating 67 includes an electrolyte. Additionally, the adhesion strength of the first adhesive coating 67 to the belt 25 is greater than the adhesion of the second adhesive coating 66 to the skin of the
30 subject for facilitating removal of the belt 25 and the electrodes 26 and 27 from the subject without causing detachment of the electrodes 26 and 27 from the belt 25.

In this embodiment of the invention the central electrode 26 is of dimensions 100mm \pm 20% in width in a circumferential direction about the torso 3, and 100mm \pm 50% height in a vertical direction. The side electrodes 27 are respectively of 75mm height \pm 20% by 100mm wide \pm 20%. Central and side electrodes 26 and 27 of these
5 dimensions have been found to be of sufficient size so that the central electrode 26 when centrally applied over the umbilicus extends across a substantial portion of the rectus abdominis and the side electrodes 27 when located centrally on the mid-axillary lines 13 and 14 or relatively close thereto covers a sufficient area of the lower thoracic nerves and the first and second lumbar nerves for providing
10 stimulation of the rectus abdominis muscles and the transversalis and oblique muscles.

The central and side electrodes 26 and 27 are supplied with release sheets (not shown) on respective opposite sides thereof for protecting the respective first and
15 second adhesive coatings 67 and 68.

Referring now to Figs. 13 to 18 various pulsed signals which can be generated by the signal generator 28 and various connections of the main and central electrodes 26 and 27 to the pulse generator 28 will now be described. Referring initially to Figs.
20 13 and 14 in this connection configuration the respective left and right side electrodes 27a and 27b which are also designated with the reference letters L and R, respectively, are independently connected to the pulse generator 28, and independently apply respective pulsed signals I_1 and I_2 to the subject which are generated by the pulse generator 28. The central electrodes 26 which is designated
25 in the reference letter U, acts as a common return electrode for returning the sum I_3 of the pulsed signals $I_1 + I_2$ to the signal generator 28, where $I_3 = I_1 + I_2$. Accordingly, in this configuration the electrodes 26 and 27 are selected in pairs where one pair is formed by the central electrode 26 and one of the side electrodes 27, and the other pair is formed by the central electrode 26 and the other of the side electrodes 27. In
30 other words the electrode pairs are the pairs R - U and L - U.

In this embodiment of the invention the duration of the pulses of each pulsed signal which is applied to the respective pairs of electrodes may be independently varied

between 50 microseconds and 1000 microseconds. The interval between pulses of the pulsed signals may also be independently varied between 5 milliseconds and 1000 milliseconds. The magnitude M of the pulses of each pulsed signal I_1 and I_2 is independently variable by the signal generator 28, and may range from 0mA to 100mA. The pulses of the respective pulsed signals I_1 and I_2 are in phase, and thus, the pulses being returned to the signal generator 28 through the central electrodes 26 is the sum of the outgoing pulses I_1 and I_2 .

Two of the control buttons 62 on the signal generator 28 provides for manual independent varying of the magnitude M of the pulses of the respective pulsed signals I_1 and I_2 , and another of the buttons 62 on the signal generator 28 provides for balancing of the magnitude of the pulses of the respective pulsed signals. A further two of the buttons 62 on the signal generator 28 provides for varying the interval between pulses of the pulsed signals. The duration of the pulses of each pulsed signal is varied by another two of the buttons 62 on the signal generator 28. The control of the magnitude, the interval between the pulses and the duration of the pulses by the signal generator 28 will not be described further, since the generation and control of such pulsed signals will be well known to those skilled in the art.

Figs. 15 and 16 illustrate an alternative connection configuration of the central and side electrodes 26 and 27 to the signal generator 28. In this configuration the electrodes 26 and 27 are selected in similar pairs as those described with reference to Figs. 13 and 14, namely, the pairs $R - U$ and $L - U$. However, only one pulsed signal I_3 is generated by the signal generator 28 and is applied to the two side electrodes 27a and 27b, and returned through the central electrode 26 which acts as a common return. In this embodiment of the invention the respective proportion I_1 and I_2 of the pulsed signals flowing through the side electrodes 27a and 27b may be similar or different, depending on the impedance between the respective side electrodes 27 and the central electrode 26 through the subject, and the impedance between the respective side electrodes 27 and the skin of the subject. The magnitude of the pulses are varied by one of the buttons 62 on the signal generator 28.

Referring now to Figs. 17 and 18 there is illustrated a further alternative connection configuration of the central and side electrodes 26 and 27 to the signal generator 28, and alternative pulsed signals generated by the signal generator 28. In this configuration the electrodes 26 and 27 are selected in pairs similar to those described with reference to Figs. 13 and 14, namely, the pairs R – U and L – U. The signal generator 28 generates two pulsed signals I_1 and I_2 which are applied respectively to the side electrodes 27a and 27b and are returned through the central electrode 26 which acts as a common return. The pulses of the pulsed signals I_1 and I_2 in this case are 180° out of phase with each other, however, the interval between the pulses of the respective pulsed signals is similar. The magnitude and duration of the pulses of the respective pulsed signals are independently variable, and as can be seen in Fig. 18 the pulses of the pulsed signal I_1 are of greater magnitude but shorter duration than the pulses of the pulsed signal I_2 .

In use, with the belt 25 laid flat and the inner side 34 facing upwardly the central electrode 26 is secured centrally in the main locating area 31. The appropriate secondary locating area 32a, 32b or 32c is selected, depending on the girth of the torso 3 of the subject, and the respective side electrodes 27 are secured to the inner side 34 of the belt 25 with the peripheral edge 33 of the side electrodes 27 aligned with the appropriate secondary locating marks 30a, 30b or 30c. Remaining release sheets are then removed from the central and side electrodes 26 and 27 and the belt 25 is offered up to the torso 3 of the subject with the central electrode 26 centrally aligned with the umbilicus 12. The belt 25 is then stretched around the torso 3 of the subject until the side electrodes 27 are centrally aligned with the respective left and right mid-axillary lines centrally between the rib cage 6 and the respective left and right iliac crests or relatively close thereto. The belt 25 is then secured to the subject by the band of hooks 38 engaging the appropriate band 39 of eyes. Figs. 11 and 12 illustrate the preferable locations of the central electrode 26 and the side electrodes 27 on the torso 3 when the belt 25 is tightly secured to the torso 3.

30

The signal generator 28 is then activated, and the desired pulsed signal or signals are selected. If the signal generator 28 is operated to provide two independent pulsed signals, the magnitude and/or duration of the pulses of the respective pulsed

signals as the case may be is adjusted to the desired level, and the interval between pulses in certain cases may be adjusted. The pulsed signals may also be balanced as desired.

- 5 It has been surprisingly found that by centrally locating the central electrode 26 over the umbilicus so that the central electrode 26 extends around the umbilicus 12, and by providing the side electrodes 27 centrally aligned with the mid-axillary lines, centrally between the rib cage 6 and the corresponding left and right iliac crests, or between the umbilicus and the mid-axillary line towards the mid-axillary line, only
10 three electrodes are required for providing adequate stimulation of the rectus abdominis muscle and the transversalis and oblique muscles for toning the muscles.

- Referring now to Figs. 19 to 27 there is illustrated a device according to another embodiment of the invention which is indicated generally by the reference numeral
15 75 for stimulating the abdominal muscles for toning thereof. The device 75 is substantially similar to the device 1, and similar components are identified by the same reference numerals. The main difference between the device 75 and the device 1 is that instead of providing a single main locating area, a pair of main locating areas, namely, a first main locating area 76 and a second main locating
20 area 77 are provided for locating respective first and second central electrodes 78 and 79, respectively on the belt 25 for location respectively above and below the umbilicus 12. Otherwise, the device with the exception of the signal generator 28 is similar to the device 1. The first and second main locating areas 76 and 77, and in turn the first and second central electrodes 78 and 79 act as the reference means for
25 locating the belt 25 on the torso 3. The belt 25 is located on the torso 3 with the umbilicus 12 located centrally between the respective first and second main locating areas 76 and 77, see Figs. 20 and 21.

- Referring now to Figs. 22 to 27 alternative connecting configurations for connecting
30 the electrodes 78, 79 and 27 to the signal generator 28 are illustrated for applying the pulsed signals to the subject through the electrodes 78, 79 and 27. The left and right side electrodes 27a and 27b are designated by the reference letters L and R, respectively, and the first and second central electrodes 78 and 79 are designated

by the reference letters U1 and U2, respectively. In Fig. 22 the first and second electrodes 78 and 79 and the side electrodes 27 are connected such that the side electrodes 27 and the first central electrode 78 effectively form one single electrode, while the second electrode 79 forms the other electrode, namely, the return electrode. In the connecting configuration of Fig. 23 the electrodes 78, 79 and 27 are connected such that the side electrodes 27 are connected together and the first and second central electrodes 78 and 79 are independently connected to the signal generator 28. In this way the electrodes are selected in pairs such that one selected pair of electrodes is formed by the side electrodes 27 which effectively act as one electrode and the second central electrodes 79 which acts as a return electrode, and the other selected pair of electrodes comprises the first central electrode 78 and the second electrode 79, which also acts as a return electrode for that selected pair of electrodes. In other words the pairs of electrodes are the pairs (RL) – U2 and U1 – U2. A first pulsed signal is applied to the selected electrode pair comprising the side electrodes 27 and the second central electrode 79, and a second pulsed signal is applied to the selected electrode pair comprising the first and second central electrode 78 and 79. The first and second pulsed signals may be identical or different and may be independently varied as discussed with reference to Figs. 13, 14, 17 and 18.

20

Referring now to Fig. 24 there is illustrated a further alternative connection configuration of the first and second central electrodes 78 and 79 and the side electrodes 27 to the signal generator 28. In this configuration the electrodes are selected in the following pairs. One selected pair comprises the side electrodes 27a and 27b whereby one of the side electrodes, namely, the left side electrode 27a acts as the return electrode, and the other electrode pair is selected from the first and second central electrode 78 and 79, whereby the second central electrode 79 acts as the return electrode. In other words the electrode pairs are the pairs R – L and U1 – U2. In this connection configuration the signal generator generates two pulsed signals independently of each other, one of which is applied to the subject through the side electrodes, while the other is applied to the subject through the first and second central electrodes 78 and 79. The two pulsed signals may be the same or different, however, in order to avoid a signal which is applied to the side electrode

27b being returned through the second electrode 79, and similarly, in order to avoid a signal applied to the first central electrodes 78 being returned through the side electrode 27a, the signals are multiplexed to the electrodes, and preferably, are 180° out of phase.

5

Referring now to Figs. 25 there is illustrated a schematic representation of various electrode pairs which may be selectively selected from the first and second central electrodes 78 and 79 and the side electrodes 27 to the signal generator 28. In this embodiment of the invention the electrodes may be selectively selected in electrode pairs as follows:

10

R - U1	L - U2
R - U2	R - L
L - U1	U1 - U2

15

The subcutaneous currents which are passed through the subject between the respective first and second central electrodes 78 and 79 and the side electrodes 27 are illustrated in Fig. 25 and designated as RU1, LU1, RU2, LU2, RL and U1U2, and are also designated by the Roman numerals I to VI. The signals generated by the signal generator 28 may be applied to the first and second central electrodes 78 and 79 and the side electrodes 27 in any or all of the six electrode pairs, and may be applied sequentially, simultaneously, or partly simultaneously and sequentially to the electrode pairs in any order for selectively stimulating the abdominal muscles. The signals may be multiplexed to the selected electrode pairs, and the signals applied to the respective electrode pairs may be different for providing different stimulation to the various abdominal muscles.

25

Referring now to Fig. 26 there is illustrated a circuit arrangement for applying signals to the subject through some or all of the electrode pairs selected from the electrodes 78, 79 and 27 described with reference to Fig. 25. In this embodiment of the invention the signal generator 28 is provided with a pair of pulse generators, namely, a first pulse generator 90 and a second pulse generator 91, which apply respective pulsed signals to the first and second central electrodes 78 and 79 and the side

30

electrodes 27 through a selecting means, namely, a matrix of switches S1 to S16. The pulsed signal from the first pulse generator 90 is applied to the electrode 78, 79 and 27 through the switches S1 to S8, while the pulsed signal from the second pulse generator 91 is applied to the electrodes 78, 79 and 27 through the switches S9 to S16. A microprocessor (not shown) in the signal generator 28 selectively operates the switches S1 to S16 for selecting the electrode pairs and for applying the respective pulsed signals from the first and second pulse generators 90 and 91 to the first and second central electrodes 78 and 79 and the side electrodes 27 in some or all of the selected pairs described with reference to Fig. 25. The switches S1 to S16 may be relays or semiconductor switches, and in certain cases may be manually operated switches. The microprocessor (not shown) also controls the first and second pulse generators 90 and 91 for determining the signals to be generated by the respective pulse generators so that the signals outputted by the pulse generators 90 and 91 may be varied for applying different pulsed signals to the different selected pairs of electrodes for providing different levels of stimulation for the various muscles of the abdomen. Thus, the subcutaneous current paths through the subject are selectable by selecting the appropriate electrode pairs, and the signal to be passed through each current path is also selectable. Thus, the current distribution and effective pulse frequency at each electrode can be optimised for the tissue it is desired to stimulate.

Fig. 27 illustrates an alternative circuit arrangement for applying signals generated by the signal generator 28 to the first and second central electrodes 78 and 79 and the side electrodes 27. This circuit comprises a selecting means provided by switches S1, S2 and S3 for applying the signals generated by the signal generator 28 to the electrodes 78, 79 and 27. The switches S1, S2 and S3 provide for the selective selection of the electrodes in the following electrode pairs:

R - U1	R - U2
L - U1	U1 - U2
L - U2	

A microprocessor (not shown) in the signal generator 28 controls the switches S1, S2 and S3, and the pulsed signals are multiplexed from a pulse generator 74 within the signal generator 28 through the switches S1, S2 and S3 under the control of the microprocessor (not shown). The switches S1, S2 and S3 may be relays or semiconductor switches. When the switches S1 and S2 are closed, and the switch S3 is closed onto the contact (a) the current paths I, II, III and IV are enabled. When the switch S3 is closed onto the contact (b) the current path V is enabled. In this circuit arrangement there is no provision for selecting the electrode pair RL for providing the current path VI.

It has been found that by providing first and second central electrodes, with the first central electrode being located just above the umbilicus and the second central electrode located just below the umbilicus in certain circumstances stimulation of the rectus abdominis muscles is enhanced.

Referring now to Figs. 28 to 30 there is illustrated a device according to a still further embodiment of the invention indicated generally by the reference numeral 80 for stimulating abdominal muscles of a subject. The device 80 is substantially similar to the device 1, and similar components are identified by the same reference numerals.

The main difference between the device 80 and the device 1 is that in this embodiment of the invention main and secondary fastening means comprising main and secondary stud fasteners 81 and 82 are provided for fastening the respective electrodes 26 and 27 to the main and secondary locating areas 31 and 32. In this embodiment of the invention each stud fastener 81 and 82 comprises a female part 83 and a male part 84. The male parts 84 are secured to and in electrical engagement with the electrodes 26 and 27, while the female parts 83 are secured to the belt 25 and provide electrical continuity between the electrodes 26 and 27 and the signal generator 28 through corresponding main and secondary cables 59 and 60.

In this embodiment of the invention one of the female parts 83 of the secondary stud fasteners 82 is provided in each of the three secondary locating areas 32a, 32b and 32c for receiving the male parts 84 with the corresponding side electrodes 27 in the

desired secondary locating area 32. The female and male parts 83 and 84 of the stud fasteners 81 and 82 are of electrically conductive material, in this case chrome plated steel. An electrically insulating coating 85 is applied over a surface 86 of each female part 83 which is exposed, and which would be likely to come into contact with the skin of a subject if it were not covered by one of the side electrodes 27. This, thus, avoids any danger of a signal applied to the female part 83 of a secondary stud fastener 82 by the signal generator 28 being transferred directly to the subject from the surface 86 of the female part 83. However, the interior of a socket 87 of each female part 83 provides good electrical continuity with a corresponding male projection 88 from the corresponding male part 84 for ensuring electrical continuity between the female and male parts 83 and 84 of the stud fasteners 81 and 82.

Use of the device 80 is similar to that of Fig. 1 once the central and side electrodes 26 and 27 have been secured to the belt 25 by the stud fasteners 81 and 82.

While the central and side electrodes have been described as comprising an electrically conductive adhesive coating on the side of the electrodes for adhering the electrodes to the skin of the subject, it is envisaged in certain cases that the electrically conductive coating may be non-adhesive, and indeed, may be of the type which would provide a low friction surface. In certain cases, it is envisaged that such an electrically conductive coating may provide adequate electrical contact between the electrodes and the subject.

While the device has been described for stimulating abdominal muscles, it will be apparent to those skilled in the art that the device by suitably adapting the attachment means may be used for stimulating other muscle groups of a subject, for example, back muscles, leg muscles, arm muscles, or indeed any other muscle group.

It will of course be appreciated that as well as being able to vary the current, duration of the pulses, the interval between the pulses, and/or other parameters of the pulsed signal, the direction of the current through the subcutaneous paths of the subject may also be reversed. It will of course be appreciated that any or all of the

subcutaneous current paths which may be selected by appropriately selecting the electrodes in appropriate selected pairs may be selected in any order, and the order and selection may vary during a treatment regime by suitably programming the microprocessor in the signal generator.

Claims

1. A device for attaching at least three electrodes (26,27,78,79) to a subject for stimulating abdominal muscles of the subject, the device comprising an attachment means (25) for extending around the torso (3) of the subject, characterised in that a
5 main locating means (31,76,77) is provided on the attachment means (25) for locating a central electrode (26,78,79) of the at least three electrodes (26,27,78,79) adjacent the umbilicus (12) of the subject, and two secondary locating means (32) are provided on the attachment means (25) disposed on respective opposite sides of the main locating means (31,76,77) for locating two corresponding side electrodes
10 (27) of the at least three electrodes (26,27,78,79) spaced apart from the central electrode (26,78,79) in a general direction towards a corresponding one of the left and right mid-axillary lines (13,14) of the torso intermediate the rib cage (6) and corresponding left and right iliac crests (8,9) so that by applying at least one pulsed signal to the subject through the respective central and side electrodes (26,27,78,79)
15 abdominal muscles of the subject are stimulated.
2. A device as claimed in Claim 1 characterised in that the secondary locating means (32) are disposed on the attachment means (25) for locating the respective side electrodes (27) towards the mid-point of the corresponding mid-axillary line
20 (13,14) between the rib cage (6) and the corresponding iliac crest (8,9).
3. A device as claimed in Claim 1 or 2 characterised in that the secondary locating means (32) are disposed on the attachment means for locating the respective side electrodes (27) adjacent the corresponding mid-axillary line (13,14).
25
4. A device as claimed in any preceding claim characterised in that the secondary locating means (32) are disposed on the attachment means for locating the respective side electrodes (27) adjacent the mid-point of the corresponding mid-axillary line (13,14) between the rib cage (6) and the corresponding iliac crest (8,9).
30
5. A device as claimed in any preceding claim characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the

central electrode (26,78,79) on the umbilicus (12) and extending around the umbilicus (12).

5 6. A device as claimed in any preceding claim characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the central electrode (26,78,79) on the umbilicus (12) and extending completely around the umbilicus (12).

10 7. A device as claimed in any preceding claim characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the central electrode (26,78,79) on the umbilicus (12), but with a greater area of the central electrode (26,78,79) located below the umbilicus (12) than above the umbilicus (12).

- 15 8. A device as claimed in any of Claims 1 to 4 characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the central electrode (26,78,79) adjacent but not on the umbilicus (12).

20 9. A device as claimed in Claim 8 characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the central electrode (79) below the umbilicus (12).

25 10. A device as claimed in Claim 8 characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the central electrode (78) above the umbilicus.

30 11. A device as claimed in Claim 8 characterised in that the main locating means (31,76,77) is disposed on the attachment means (25) for locating the central electrode (78,79) both below and above the umbilicus (12).

12. A device as claimed in any preceding claim characterised in that a reference means (31) is provided on the attachment means (25) for locating the attachment means on the torso (3) relative to an anatomical reference (12).

13. A device as claimed in Claim 12 characterised in that the reference means (31) is provided for locating the attachment means (25) circumferentially around the torso (3).
- 5 14. A device as claimed in Claim 12 or 13 characterised in that the reference means (31) is provided for locating the attachment means (25) vertically along the torso (3).
- 10 15. A device as claimed in any of Claims 12 to 14 characterised in that the main locating means (31) acts as the reference means (31) for locating the attachment means (25) relative to the anatomical reference (12) provided by the umbilicus.
- 15 16. A device as claimed in any preceding claim characterised in that the main locating means (31) comprises a first main locating means (76) and a second main locating means (77) for locating respective corresponding first and second central electrodes (78,79) adjacent the umbilicus (12) of the subject.
- 20 17. A device as claimed in Claim 16 characterised in that the first main locating means (76) is provided for locating the first central electrode (78) above the umbilicus (12), and the second main locating means (77) is provided for locating the second central electrode (78) below the umbilicus (12).
- 25 18. A device as claimed in any preceding claim characterised in that two sets of at least two secondary locating means (32) are disposed on the respective opposite sides of the main locating means (31,76,77) for facilitating selective location of the respective side electrodes (27) for accommodating different girths of torso.
- 30 19. A device as claimed in Claim 18 characterised in that each set of secondary locating means (32) comprises three secondary locating means (32).
20. A device as claimed in any preceding claim characterised in that portions (47) of the attachment means (25) on respective opposite sides of the main locating

means (31,76,77) between the main locating means (31,76,77) and the corresponding secondary locating means (31) are of resilient material for facilitating resilient stretching of the attachment means (25) between the main and corresponding secondary locating means.

5

21. A device as claimed in Claim 20 characterised in that the attachment means (25) is of a resilient material for facilitating stretching of the attachment means (25) around the torso, the resilient portions (47) of the attachments means (25) being of greater stretchability than that of the rest of the attachment means (25).

10

22. A device as claimed in any preceding claim characterised in that a main electrically conductive contact means (45) is provided on the attachment means (25) corresponding to each main locating means (31,76,77) for receiving the at least one pulsed signal and for relaying the signal to the corresponding central electrode (26,78,79).

15

23. A device as claimed in Claim 22 characterised in that each main contact means (45) is located within the corresponding main locating means (31,76,77).

20

24. A device as claimed in any preceding claim characterised in that two secondary electrically conductive contact means (46) are provided on the attachment means (25) for receiving the at least one pulsed signal and for relaying the signal to the respective corresponding side electrodes (27).

25

25. A device as claimed in Claim 24 characterised in that each secondary contact means (46) is located adjacent the corresponding secondary locating means (32) or the corresponding set of secondary locating means (32).

30

26. A device as claimed in Claim 24 or 25 characterised in that each secondary contact means (46) is located adjacent the corresponding set of secondary locating means (32) so that irrespective of which secondary locating means (32) is selected for locating the corresponding side electrode (27) the side electrode is in electrically conductive engagement with the secondary contact means (46).

27. A device as claimed in any preceding claim characterised in that each main and secondary locating means (31,76,77,32) is provided by a visually perceptive locating means (29,30).

5

28. A device as claimed in any preceding claim characterised in that each main and secondary locating means (31,76,77,32) is formed by a corresponding locating mark (29,30) on the attachment means (25).

10 29. A device as claimed in Claim 28 characterised in that each locating mark (29,30) defines an outline of a part of the periphery of the corresponding electrode (26,78,79,27) corresponding to the locating means (31,76,77,32).

30. A device as claimed in any preceding claim characterised in that each
15 locating means (31,76,77,32) is adapted for locating a patch type electrode (26,78,79,27).

31. A device as claimed in any preceding claim characterised in that the device
20 comprises the at least three electrodes (26,78,79,27).

20

32. A device as claimed in Claim 31 characterised in that each electrode (26,78,79,27) is a patch type electrode.

33. A device as claimed in Claim 31 or 32 characterised in that each side
25 electrode (27) is sized to cover at least a portion of the corresponding lower thoracic nerves and the corresponding first and second lumbar nerves.

34. A device as claimed in any of Claims 31 to 33 characterised in that each
30 central electrode (26,78,79) is sized to extend substantially across the rectus abdominus muscle.

35. A device as claimed in any of Claims 31 to 34 characterised in that each electrode (26,78,79,27) defines an area of contact over which the electrode makes

direct electrical contact with the subject, the area of contact of each side electrode (27) being such as not to exceed the area of contact of the or both central electrodes (26,78,79).

5 36. A device as claimed in Claim 35 characterised in that the area of contact of each side electrode (27) does not exceed one third of the area of contact of the or both central electrodes (26,78,79).

10 37. A device as claimed in Claim 35 or 36 characterised in that each side electrode (27) is of width in a circumferential direction relative to the torso of the subject in the range of 50mm to 150mm, and is of length in a vertical direction relative to the torso of the subject in the range of 80mm to 120mm.

15 38. A device as claimed in any of Claims 31 to 37 characterised in that a first electrically conductive coating (67) is provided on one side of each electrode (26,78,79,27) for electrically connecting the electrode to the corresponding contact means (45,46).

20 39. A device as claimed in Claim 38 characterised in that the first coating (67) is a gel type coating containing an electrolyte solution for enhancing electrical contact between the electrode and the corresponding contact means.

25 40. A device as claimed in any of Claims 31 to 39 characterised in that a second electrically conductive coating (68) is provided on the other side of each electrode (26,78,79,27) for electrically connecting the electrode to the torso of the subject.

41. A device as claimed in Claim 40 characterised in that the second coating (68) is a gel type coating.

30 42. A device as claimed in Claim 40 or 41 characterised in that the second coating (68) is an adhesive coating.

43. A device as claimed in any of Claims 38 to 42 characterised in that the first coating (67) is an adhesive coating.

5 44. A device as claimed in Claim 43 characterised in that the bond strength of the first coating (67) to the attachment means (25) is greater than the bond strength of the second coating (68) to the torso (3) for facilitating removal of the attachment means (25) and the electrodes (26,78,79,27) located thereon from the torso of the subject.

10 45. A device as claimed in any of Claims 38 to 44 characterised in that the electrodes (26,78,79,27) are pre-coated with the respective first and second coatings (67,68).

15 46. A device as claimed in any preceding claim characterised in that a receiving means (54) is provided in the attachment means for receiving a signal generating means (28) for generating the at least one pulsed signal.

20 47. A device as claimed in Claim 46 characterised in that a main electrical connecting means (59) extends between the receiving means (54) and each main contact means (45) for relaying the at least one pulsed signal from the signal generating means (28) to the corresponding main contact means (45).

25 48. A device as claimed in Claim 46 or 47 characterised in that a secondary electrical connecting means (60) extends between the receiving means (54) and each secondary contact means (46) for relaying the at least one pulsed signal from the signal generating means to the corresponding secondary contact means (46).

30 49. A device as claimed in Claim 47 or 48 characterised in that each electrical connecting means (59,60) is located within the attachment means (25).

50. A device as claimed in any of Claims 46 to 49 characterised in that the receiving means (54) is a releasable receiving means for releasably receiving the signal generating means (28).

51. A device as claimed in Claim 50 characterised in that the receiving means (54) receives the signal generating means with a snap fit action.

5 52. A device as claimed in any of Claims 46 to 51 characterised in that the signal generating means (28) for generating the at least one pulsed signal is provided in the receiving means (54).

10 53. A device as claimed in Claim 52 characterised in that a means (S1 to S16) is provided for selectively selecting at least one pair of electrodes (26,78,79,27) from the at least three electrodes (26,78,79,27) through which the at least one pulsed signal is applied to the subject.

15 54. A device as claimed in Claim 53 characterised in that the at least one pulsed signal is applied simultaneously to each of the selected pairs of electrodes (26,78,79,27).

20 55. A device as claimed in Claim 53 characterised in that the at last one pulsed signal is applied sequentially to each of the selected pairs of electrodes (26,78,79,27).

25 56. A device as claimed in any of Claims 53 to 55 characterised in that one of the selected pairs of the electrodes comprises one side electrode (27) and the central electrode (26,78,79), and another selected pair of the electrodes comprises the other side electrode (27) and the central electrode (26,78,79).

57. A device as claimed in any of Claims 53 to 56 characterised in that one of the selected pairs of electrodes comprises the two side electrodes (27).

30 58. A device as claimed in any of Claims 53 to 57 characterised in that one of the selected pairs of electrodes comprises one of the side electrodes (27) and one of the first and second central electrodes (78,79), and another of the selected pairs of

electrodes comprises the other of the side electrodes (27) and the other of the first and second central electrodes (78,79).

59. A device as claimed in any of Claims 53 to 58 characterised in that one of the
5 selected pairs of electrodes comprises the first and second central electrodes
(78,79) which act as one single electrode and one of the side electrodes (27), and
another of the selected pairs of electrodes comprises the first and second central
electrodes (78,79) which act as one single electrode and the other side electrode
(27).

10

60. A device as claimed in any of Claims 53 to 59 characterised in that one of the
selected pairs of electrodes comprises the first and second central electrodes
(78,79).

15 61. A device as claimed in any of Claims 53 to 60 characterised in that the
pulsed signals generated by the signal generating means (28) for applying to the
respective pairs of electrodes (26,78,79,27) may be the same or different.

62. A device as claimed in any of Claims 52 to 61 characterised in that each
20 pulsed signal comprises a plurality of pulses at intervals in the range of 5
milliseconds to 1000 milliseconds.

63. A device as claimed in Claim 62 characterised in that each pulsed signal
comprises a plurality of pulses at intervals in the range of 20 milliseconds to 40
25 milliseconds.

64. A device as claimed in Claim 63 characterised in that each pulsed signal
comprises a plurality of pulses at intervals of approximately 30 milliseconds \pm 20%.

30 65. A device as claimed in any of Claims 52 to 61 characterised in that the
interval between pulses of each pulsed signal is adjustable.

66. A device as claimed in any of Claims 52 to 61 characterised in that each pulsed signal comprises pulses of duration in the range of 10 microseconds to 200000 microseconds.

5 67. A device as claimed in Claim 66 characterised in that each pulsed signal comprises pulses of duration in the range of 50 microseconds to 1000 microseconds.

68. A device as claimed in Claim 67 characterised in that each pulsed signal
10 comprises pulses of duration in the range of 100 microseconds to 500 microseconds.

69. A device as claimed in Claim 68 characterised in that each pulsed signal comprises pulses of duration of approximately 300 milliseconds \pm 20%.

15 70. A device as claimed in any of Claims 52 to 69 characterised in that the duration of each pulsed signal is adjustable.

71. A device as claimed in any of Claims 52 to 70 characterised in that each
20 pulsed signal comprises a plurality of pulses of magnitude in the range of 0mA to 100mA.

72. A device as claimed in any of Claims 52 to 71 characterised in that the magnitude of each pulse of each pulsed signal is adjustable.

25 73. A device as claimed in any preceding claim characterised in that the attachment means (25) comprises a belt (25).

74. A device as claimed in any preceding claim characterised in that a securing
30 means (38,39) is provided on the belt (25) for securing the belt around the torso (3) of the subject.

75. A device as claimed in any preceding claim characterised in that a main fastening means (81) is provided corresponding to each main locating means (31,76,77) for fastening a corresponding central electrode (26,78,79) to the attachment means (25) adjacent the corresponding main locating means (30,76,77).

5

76. A device as claimed in any preceding claim characterised in that two secondary fastening means (82) are provided in the attachment means (25) for fastening the respective side electrodes to the attachment means adjacent the corresponding selected secondary locating means (32).

10

77. A device as claimed in Claim 75 or 76 characterised in that each fastening means (81,82) comprises a stud fastener.

78. A device as claimed in Claim 77 characterised in that each stud fastener comprises a female part (83) and a male part (84), the female part (83) being secured to the attachment means (25).

15

79. A device as claimed in Claim 77 or 78 characterised in that each stud fastener (81,82) is electrically conductive so that the female part (83) of the stud fasteners form the corresponding contact means.

20

80. A device as claimed in Claim 78 or 79 characterised in that an exposed surface (86) of the female part (83) of each stud fastener is of electrically insulating material (85).

25

81. A device as claimed in Claim 80 characterised in that the exposed surface (86) of each female part (83) of each stud faster is coated with an electrically insulating coating (85).

30

82. A stud fastener for use in the device as claimed in any of Claims 75 to 81 characterised in that the stud fastener (81,82) comprises a male part (84) for attaching to a corresponding electrode (26,78,79,27), and a female part (84) for attaching to the attachment means (25).

83. A stud fastener as claimed in Claim 83 characterised in that the male and female parts (83,84) of the stud fastener (81,82) engage each other with electrically conductive engagement.

5

84. A stud fastener as claimed in Claim 82 or 83 characterised in that an exposed external surface (86) of the female part (83) of the stud fastener (81,82) which abuts the male part (84) of the stud fastener is of electrically insulating material (85).

10

85. A stud fastener as claimed in Claim 84 characterised in that the electrically insulating material is provided by an electrically insulated coating (85) on the exposed abutting surface (86).

15

86. A method for stimulating abdominal muscles of a subject, the method comprising passing at least one pulsed signal subcutaneously through the subject between selected electrodes (26,78,79,27) of at least three electrodes (26,78,79,27), one of the at least three electrodes being a central electrode (26,78,79) located adjacent the umbilicus (12) of the subject, and the other two electrodes being side electrodes (27) located on the subject spaced apart from the central electrode (26,78,79) on respective sides thereof in a general direction towards a

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corresponding one of the left and right mid-axillary lines (13,14) of the torso (3) intermediate the rib cage (6) and corresponding left and right iliac crests (8,9).

25

87. A method as claimed in Claim 86 characterised in that each side electrode (27) is located towards the mid-point of the corresponding mid-axillary line (13,14) between the rib cage (6) and the corresponding iliac crest (8,9).

30

88. A method as claimed in Claim 86 or 87 characterised in that each side electrode (27) is located adjacent the corresponding mid-axillary line (13,14).

89. A method as claimed in any of Claims 86 to 88 characterised in that each side electrode (27) is located adjacent the mid-point of the corresponding mid-axillary line (13,14) between the rib cage (6) and the corresponding iliac crest (8,9).
- 5 90. A method as claimed in any of Claims 86 to 89 characterised in that the central electrode (26,78,79) is located on the umbilicus (12) and extends around the umbilicus.
- 10 91. A method as claimed in any of Claims 86 to 90 characterised in that the central electrode (26,78,79) is located on the umbilicus (12) and extends completely around the umbilicus.
- 15 92. A method as claimed in any of Claims 86 to 91 characterised in that the central electrode (26,78,79) is located on the umbilicus (12), but with a greater area of the central electrode (26,78,79) located below the umbilicus (12) than above the umbilicus.
- 20 93. A method as claimed in any of Claims 86 to 89 characterised in that the central electrode (26,78,79) is located adjacent but not on the umbilicus (12).
94. A method as claimed in Claim 93 characterised in that the central electrode (26,78,79) is located below the umbilicus (12).
- 25 95. A method as claimed in Claim 93 characterised in that the central electrode (26,78,79) is located above the umbilicus (12).
96. A method as claimed in Claim 93 characterised in that the central electrode (26,78,79) is located both below and above the umbilicus (12).
- 30 97. A method as claimed in any of Claims 86 to 96 characterised in that the central electrode is provided by two electrodes, namely, a first central electrode (78) and a second central electrode (79), both of which are located adjacent the umbilicus (12).

98. A method as claimed in Claim 97 characterised in that the first central electrode (78) is located above the umbilicus (12) and the second central electrode (79) is located below the umbilicus (12).

5

99. A method as claimed in any of Claims 86 to 98 characterised in that the at least one pulsed signal is applied to the subject so that the signal passes subcutaneously through the subject between at least one selected pair of the at least three electrodes (26,78,79,27).

10

100. A method as claimed in Claim 99 characterised in that the at least one pulsed signal is applied simultaneously to each of the selected pairs of electrodes (26,78,79,27).

15

101. A method as claimed in Claim 99 characterised in that the at last one pulsed signal is applied sequentially to each of the selected pairs of electrodes (26,78,79,27).

20

102. A method as claimed in any of Claims 99 to 101 characterised in that one of the selected pairs of electrodes comprises one side electrode (27) and the central electrode (26,78,79), and another selected pair of electrodes comprises the other side electrode (27) and the central electrode (26,78,79).

25

103. A method as claimed in any of Claims 99 to 102 characterised in that one of the selected pairs of electrodes comprises the two side electrodes (27).

30

104. A method as claimed in any of Claims 99 to 103 characterised in that one of the selected pairs of electrodes comprises one of the side electrodes (27) and one of the first and second central electrodes (78,79), and another of the selected pairs comprises the other of the side electrodes (27) and the other of the first and second central electrodes (78,79).

105. A method as claimed in any of Claims 99 to 104 characterised in that one of the selected pairs of electrodes comprises the first and second central electrodes (78,79) which act as one single electrode and one of the side electrodes (27), and another of the selected pairs of electrodes comprises the first and second central electrodes (78,79) which act as one single electrode and the other side electrode (27).

106. A method as claimed in any of Claims 99 to 105 characterised in that one of the selected pairs of electrodes comprises the first and second central electrodes (78,79).

107. A method as claimed in any of Claims 99 to 106 characterised in that the pulsed signals applied to the respective pairs of electrodes (26,78,79,27) may be the same or different.

108. A method as claimed in any of Claims 86 to 107 characterised in that each pulsed signal comprises a plurality of pulses at intervals in the range of 5 milliseconds to 1000 milliseconds.

109. A method as claimed in Claim 108 characterised in that each pulsed signal comprises a plurality of pulses at intervals in the range of 20 milliseconds to 40 milliseconds.

110. A method as claimed in Claim 109 characterised in that each pulsed signal comprises a plurality of pulses at intervals of approximately 30 milliseconds \pm 20%.

111. A method as claimed in any of Claims 86 to 110 characterised in that the interval between pulses of each pulsed signal is adjustable.

112. A method as claimed in any of Claims 86 to 111 characterised in that each pulsed signal comprises pulses of duration in the range of 10 microseconds to 200000 microseconds.

113. A method as claimed in Claim 112 characterised in that each pulsed signal comprises pulses of duration in the range of 50 microseconds to 1000 microseconds.

5 114. A method as claimed in Claim 113 characterised in that each pulsed signal comprises pulses of duration in the range of 100 microseconds to 500 microseconds.

115. A method as claimed in Claim 114 characterised in that each pulsed signal
10 comprises pulses of duration of approximately 300 milliseconds \pm 20%.

116. A method as claimed in any of Claims 86 to 115 characterised in that the duration of each pulsed signal is adjustable.

15 117. A method as claimed in any of Claims 86 to 116 characterised in that each pulsed signal comprises a plurality of pulses of magnitude in the range of 0mA to 100mA.

118. A method as claimed in any of Claims 86 to 117 characterised in that the
20 magnitude of each pulse of each pulsed signal is adjustable.

119. An electrotherapeutic device for stimulating muscles of a muscle group of a subject, the device comprising a plurality of electrodes (26,78,79,27) for placing on the subject for applying at least one pulsed signal to the subject for stimulating the
25 muscles, a signal generating means (28) for generating the at least one pulsed signal, and a selecting means (S1 to S16) for selectively selecting the electrodes (26,78,79,27) in electrode pairs and for selectively applying the at least one pulsed signal to the selected electrode pairs (26,78,79,27) for selective stimulation of the muscles of the muscle group.

30

120. A device as claimed in Claim 119 characterised in that the selecting means comprises a switching means (S1 to S16) for selectively switching the at least one pulsed signal from the signal generating means (28) to the electrodes (26,78,79,27).

121. A method for stimulating muscles of a muscle group of a subject, the method comprising passing at least one pulsed signal subcutaneously through the subject between selected electrodes (26,78,79,27) of at least three electrodes (26,78,79,27),
5 characterised in that the electrodes (26,78,79,27) are selectively selected in electrode pairs for selectively stimulating selected muscles of the muscle group.

122. A method as claimed in Claim 121 characterised in that the electrode pairs are sequentially selected from the electrodes (26,78,79,27).
10

123. A method as claimed in Claim 121 characterised in that the electrode pairs are simultaneously selected from the electrodes (26,78,79,27).

ABSTRACT

"An electrotherapy device and method"

A device (1) for electrotherapeutically stimulating abdominal muscles of a subject
5 comprises a belt (25) which locates a central electrode (26) and a pair of side
electrodes (27) on the abdomen of the subject. A signal generator (28) also attached
to the belt (25) and connected to the central and side electrodes (26,27) generates
pulsed signals which are applied to the subject through the central and side
electrodes (26,27) for muscle stimulation. The central electrode (26) and the side
10 electrodes (27) are located in the belt (25) so that when the belt (25) is located on
the torso (3) with the central electrode (26) over the umbilicus (12) and appropriately
stretched around the torso (3) the side electrodes (27) are aligned with respective
left and right mid-axillary lines (13,14) between the rib cage (6) and left and right iliac
crests (8,9) of the subject. With this arrangement of the central and side electrodes
15 (26,27) it has been found that adequate stimulation of the rectus abdominis, the
transversalis and the oblique muscles of the abdomen are stimulated for muscle
toning with only three electrodes.

Figs. 5 to 10 to accompany abstract.

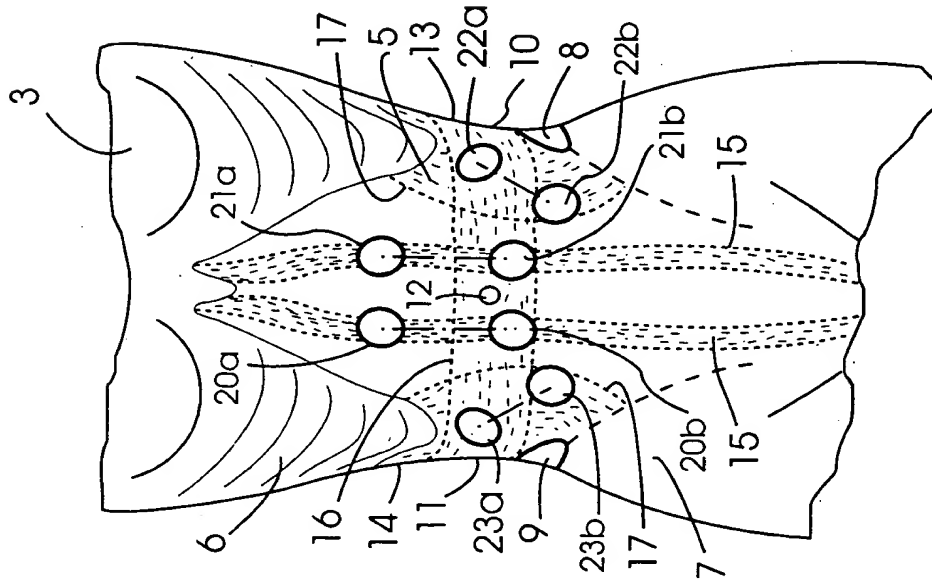


Fig. 1

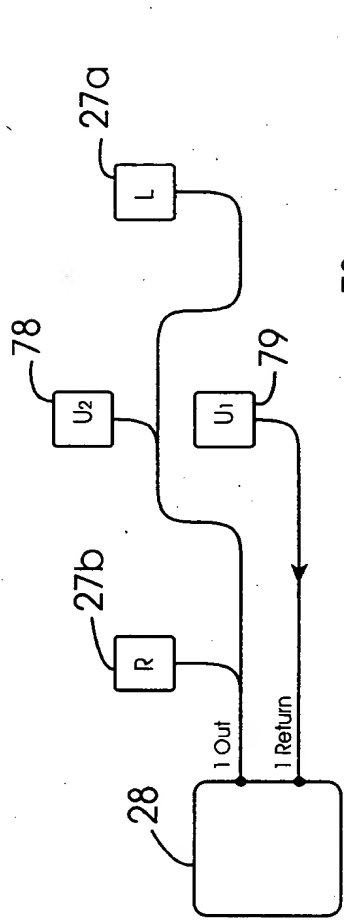


Fig. 22

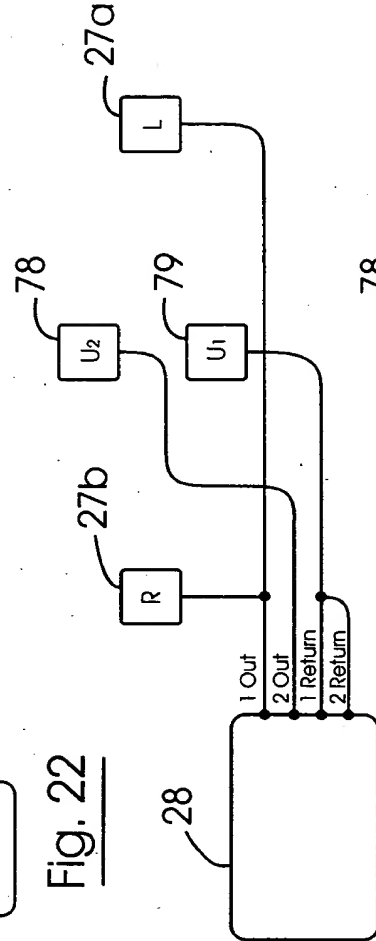


Fig. 23

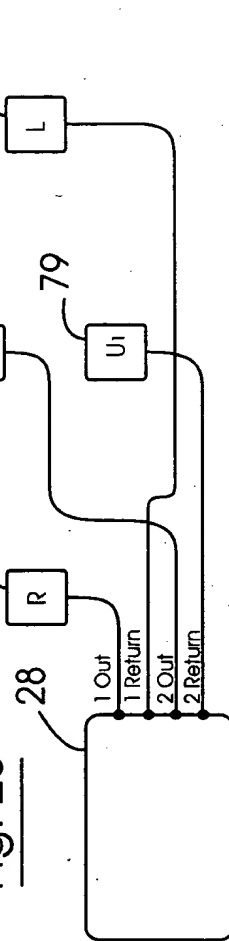


Fig. 24

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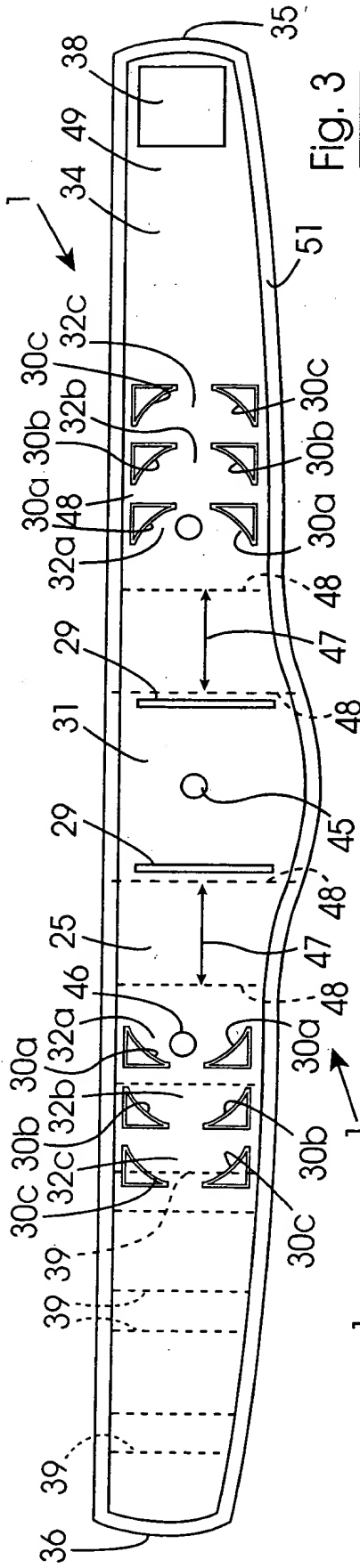


Fig. 3

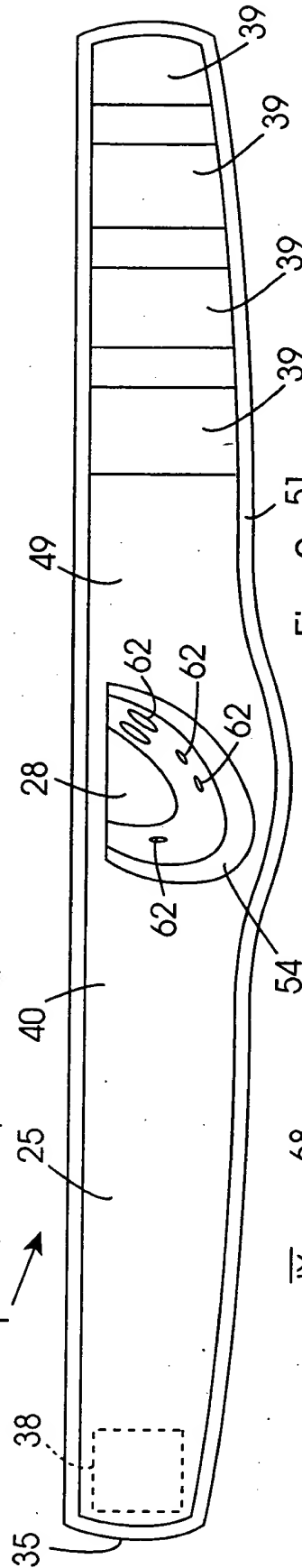


Fig. 2

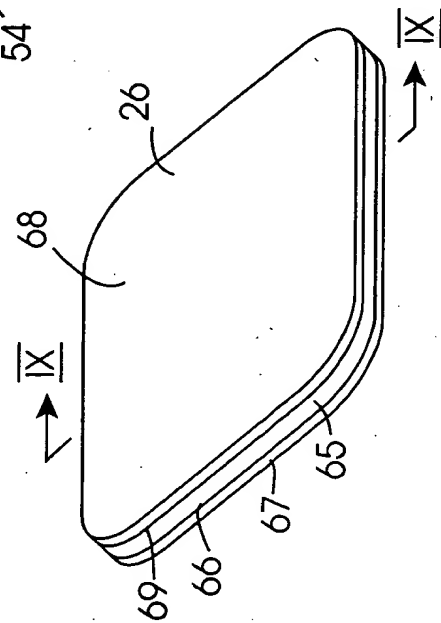


Fig. 7

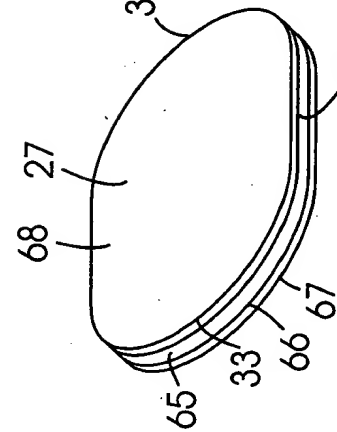


Fig. 8

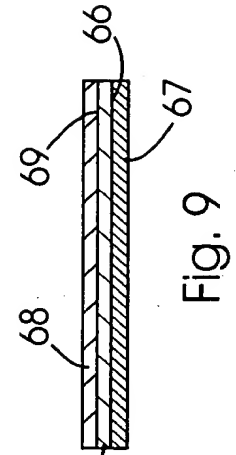


Fig. 9

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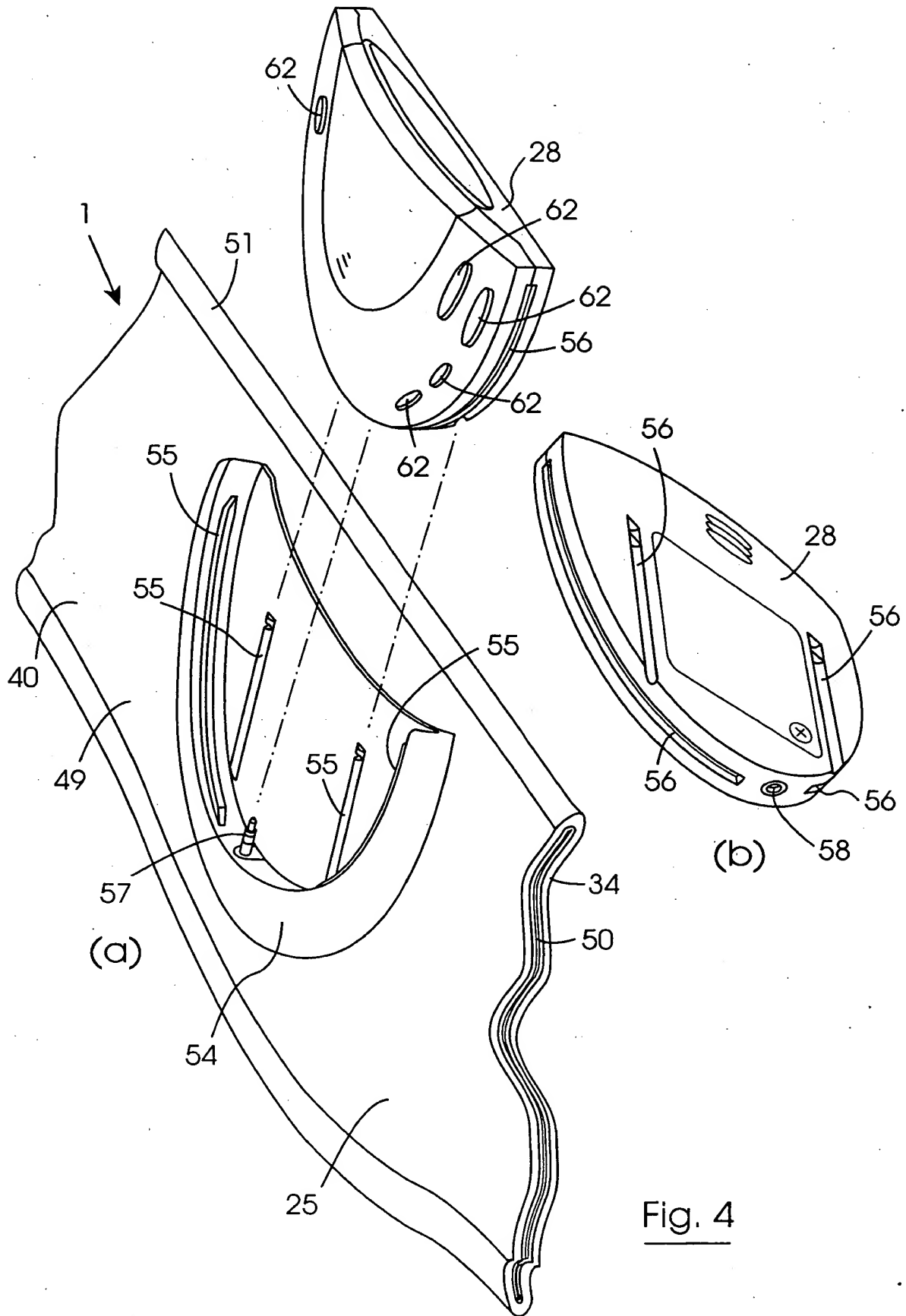


Fig. 4

Fig. 6

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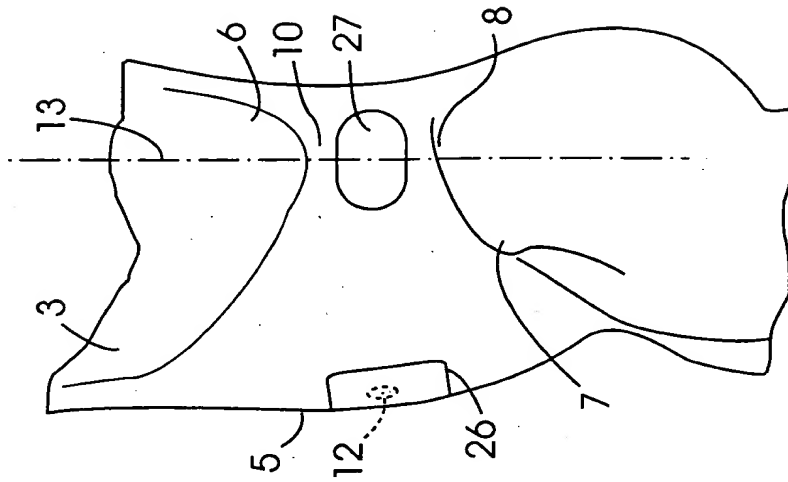


Fig. 10

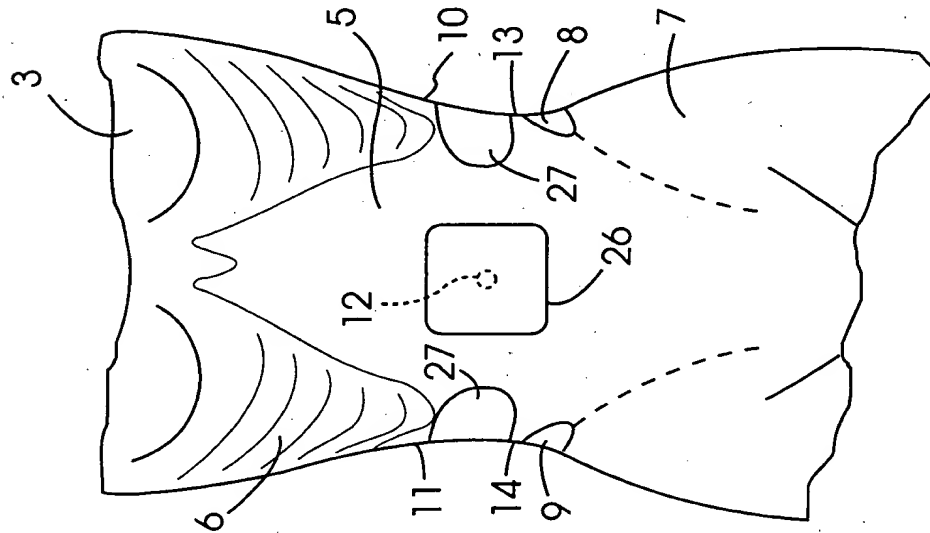


Fig. 11

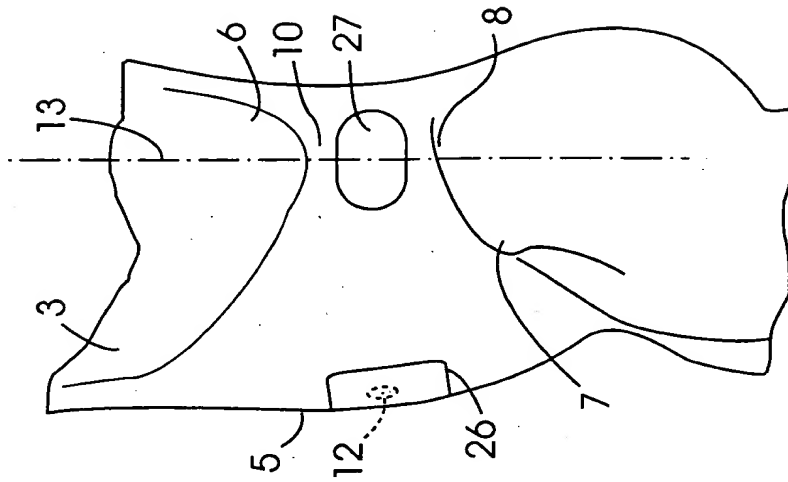


Fig. 12

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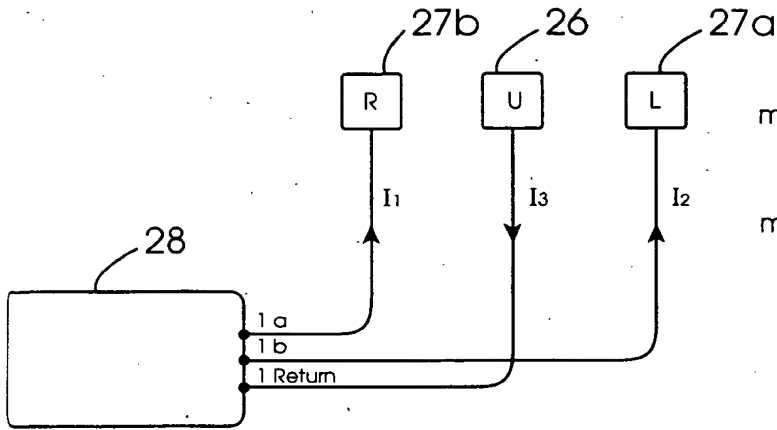


Fig. 13

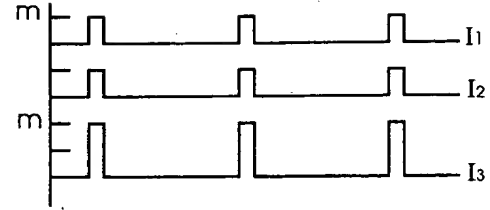


Fig. 14

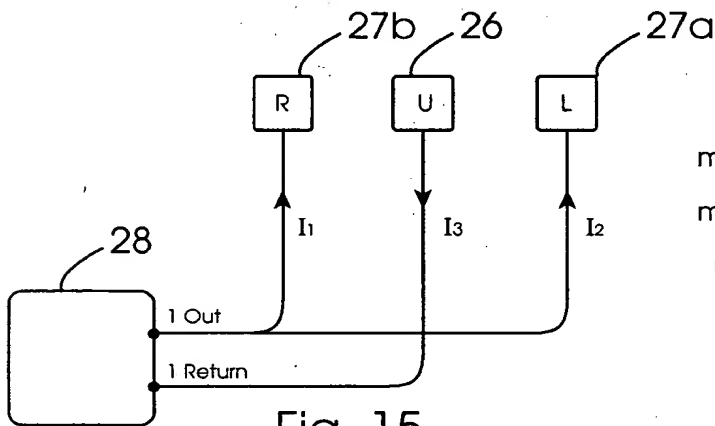


Fig. 15

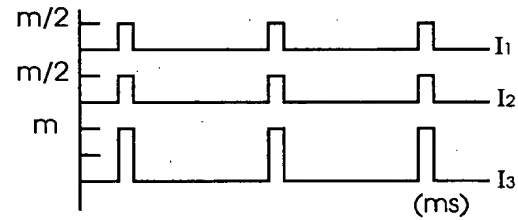


Fig. 16

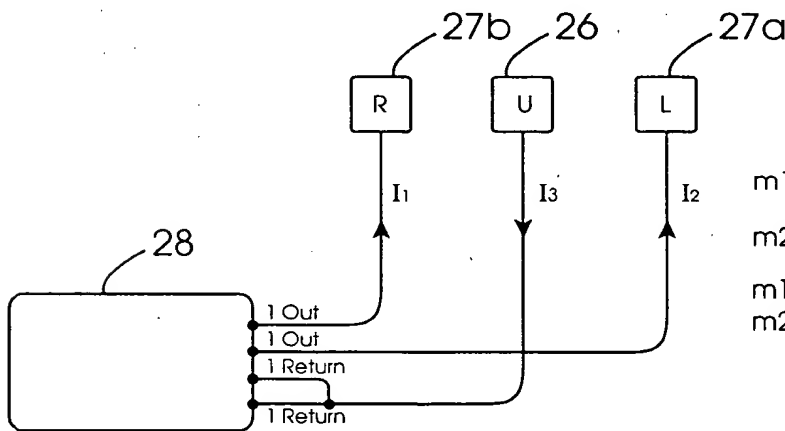


Fig. 17

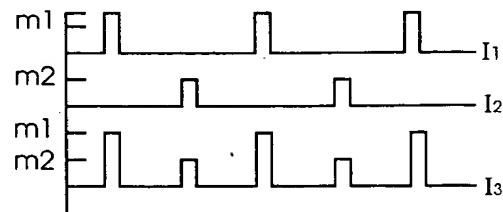


Fig. 18

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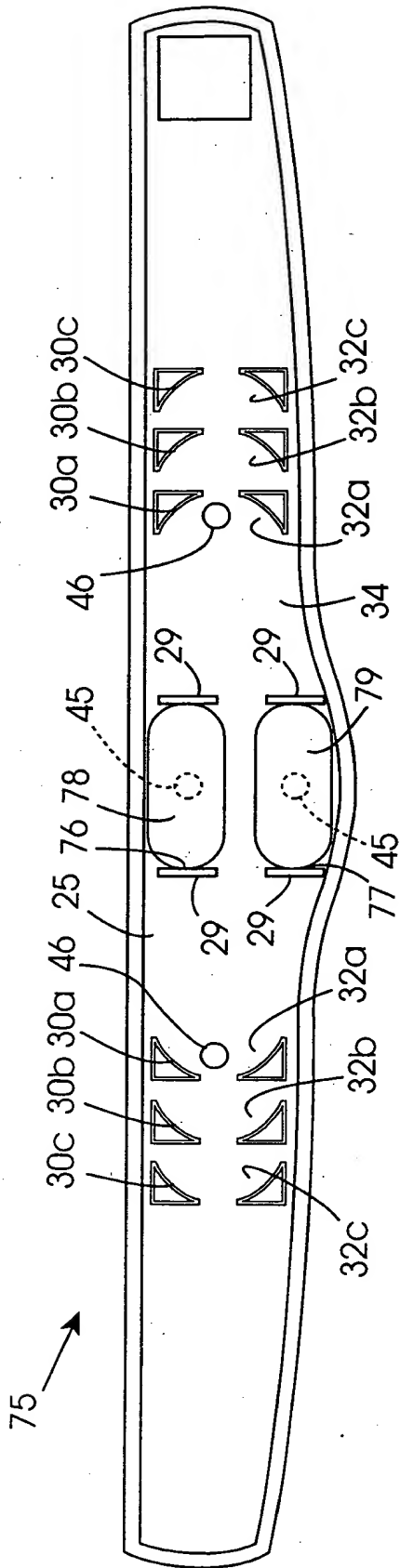


Fig. 19

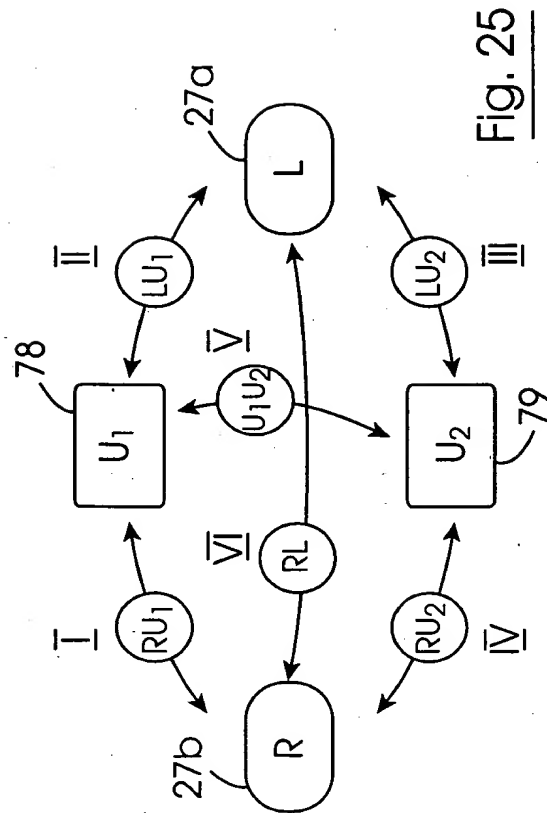


Fig. 25

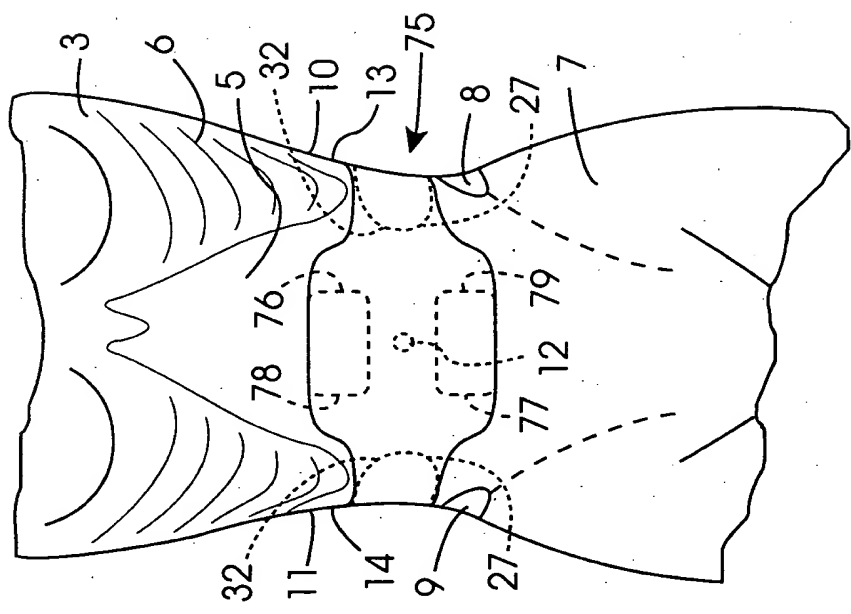


Fig. 20

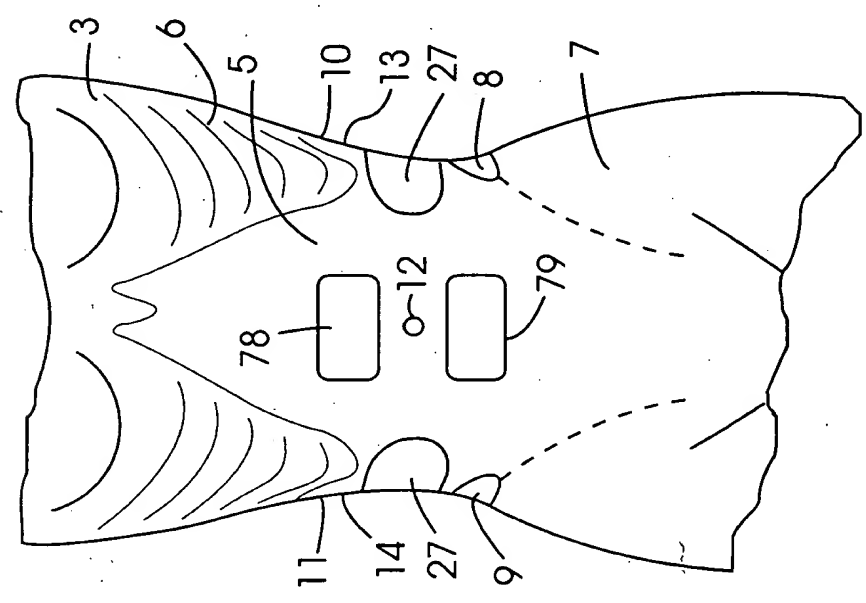


Fig. 21

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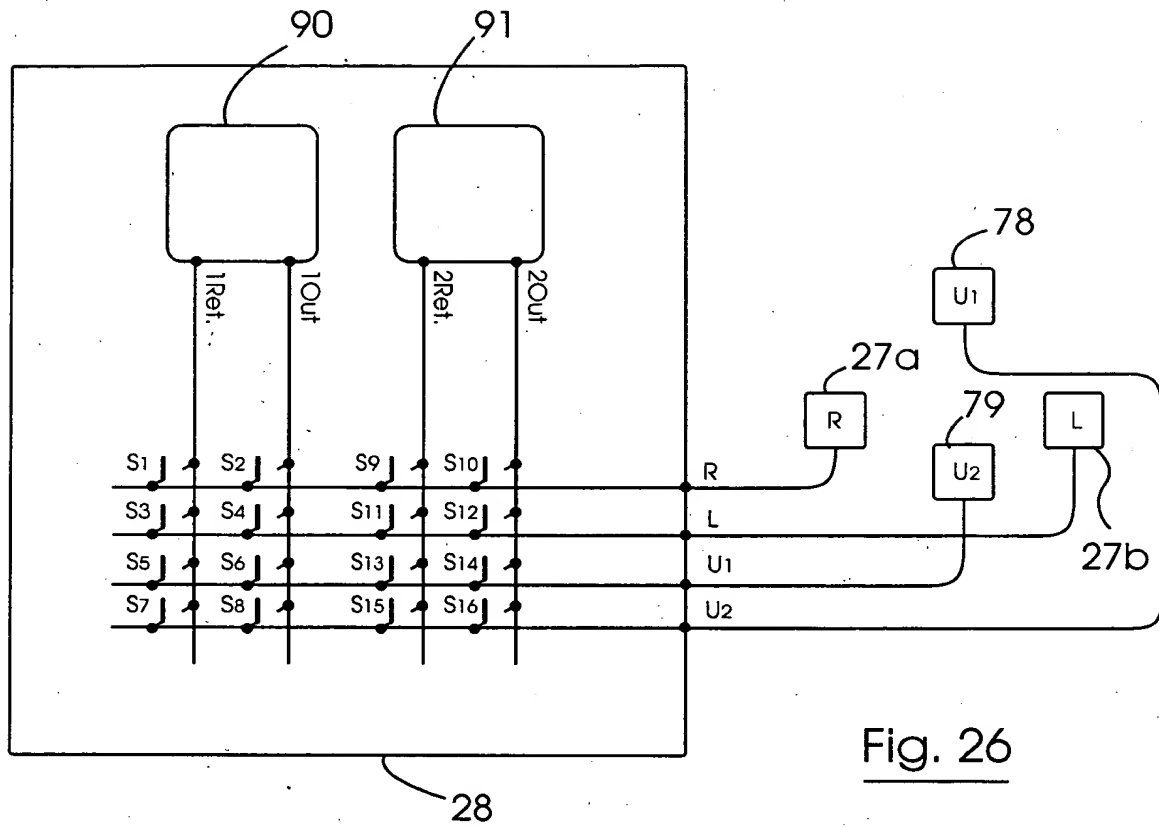


Fig. 26

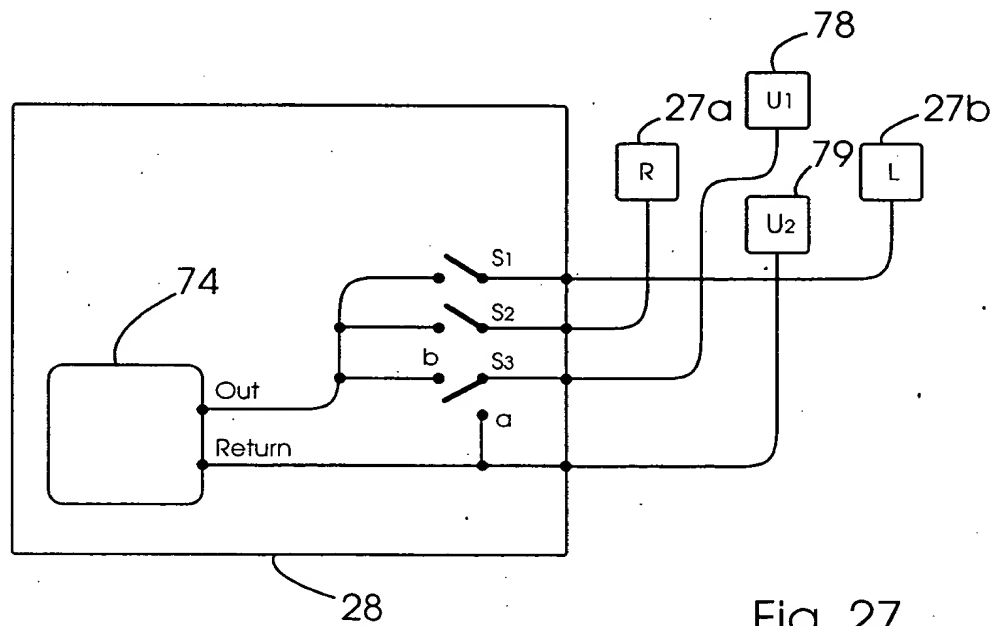


Fig. 27

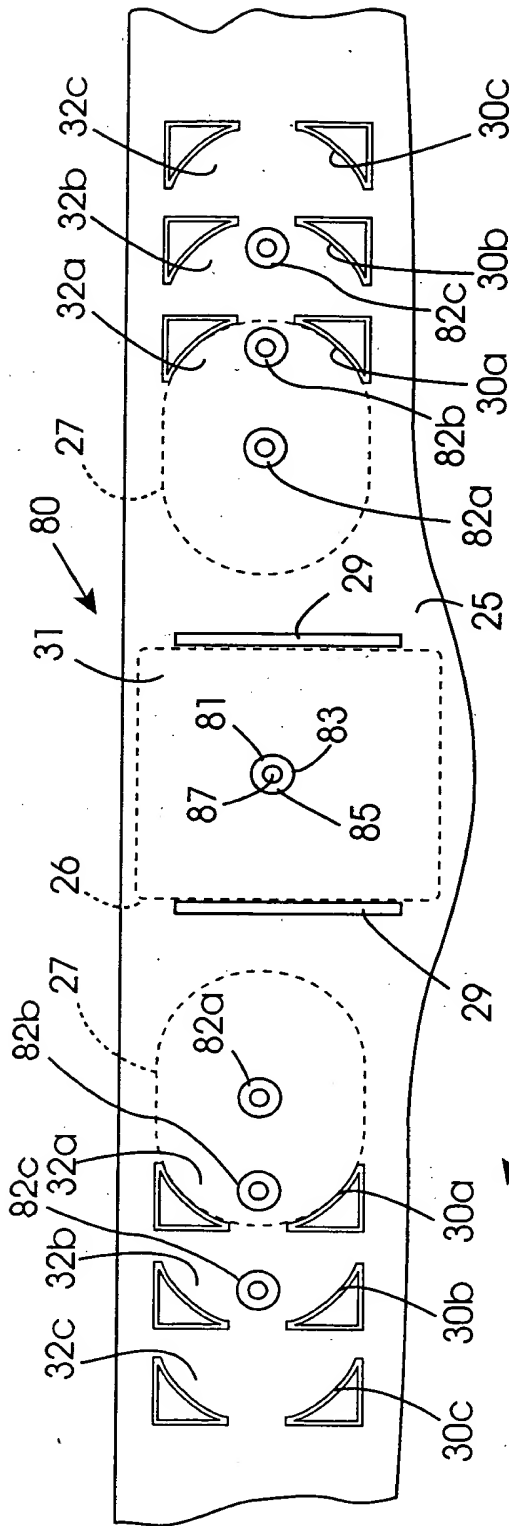


Fig. 28

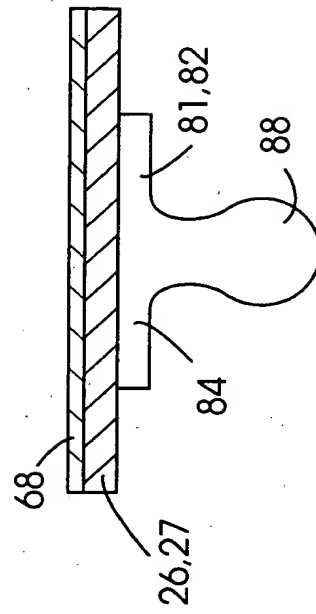


Fig. 29

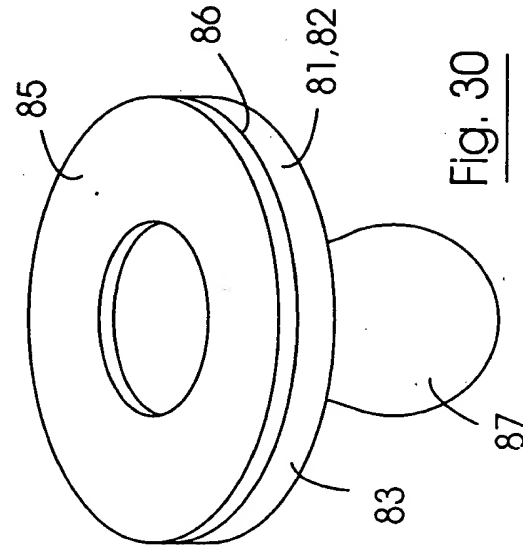


Fig. 30

EXHIBIT J



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:)
Michael Conor MINOGUE et al.)
U.S. Patent No. : 7,069,089)
Issue Date: June 27, 2006)
Application No.: 09/902,287)
Filed: July 10, 2001)
Title: ABDOMINAL BELT WITH)
ADJUSTABLE ELECTRODES)

Commissioner for Patents
Alexandria, VA 22314

**SUBMISSION OF REVOCATION OF ORIGINAL POWER OF ATTORNEY
AND GRANT OF NEW POWER OF ATTORNEY**

Sir:

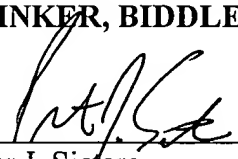
Enclosed is a copy of the Revocation of Original Power of Attorney and Grant of New Power of Attorney by the Assignee.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 50-0573.

Respectfully submitted,

DRINKER, BIDDLE & REATH LLP

Dated: August 2, 2007

By: 
Peter J. Sistare
Registration No. 48,183

CUSTOMER NO. 55694
DRINKER, BIDDLE & REATH LLP
1500 K Street, N.W., Suite 1100
Washington, D.C. 20005-1209
Tel: (202) 842-8800
Fax: (202) 842-8465



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assignee: **BIO-MEDICAL RESEARCH LTD.**

Commissioner for Patents

Washington, D.C. 20231

REVOCATION AND NEW POWER OF ATTORNEY

Under 37 CFR §3.73(b), **BIO-MEDICAL RESEARCH LTD.**, an Irish company, certifies that it is the assignee of 100% of the right, title and interest in the patent applications and issued patents identified in the following chart by virtue of respective Assignment documents for each listed application and patent from the inventor(s) to **BIO-MEDICAL RESEARCH LTD.** submitted to the U.S. Patent and Trademark Office. The dates on which the assignments were submitted and the reel/frame numbers at which the assignments were recorded are indicated in the chart below.

Filing Date	Attorney Docket No.	Application No.	Patent No. (if applicable)	Issue Date (if applicable)	Recordation Info. Date; Reel/Frame
10 Jul 2001	200415-0001	09/902,287	7,069,089	27 Jun 2006	26 Oct 2001; 012531/0248
12 May 2006	200415-0001-04	11/434,436			26 Oct 2001; 012479/0467
10 Jul 2001	200415-0004	09,902,186	6,728,577	27 Apr 2004	26 Oct 2001; 012479/0467
10 Jul 2001	200415-0005	09/902,281	6,885,896	26 Apr 2005	29 Oct. 2001; 012358/0535
10 Jul 2001	200415-0006	09/902,225	6,760,629	06 Jul 2004	26 Oct 2001; 012479/0824

The undersigned has reviewed all documents in the chain of title of the patent applications and patents identified above and, to the best of the undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned, whose title is supplied below, is empowered to act on behalf of the assignee.

Assignee : BIO-MEDICAL RESEARCH LTD.

Page : 2

Acting on behalf of the assignee, the undersigned hereby revokes all powers of attorney previously granted in these applications and patents and appoints:

Customer Number 055694
DRINKER BIDDLE & REATH LLP
1500 K Street, N.W., Suite 1100
Washington, DC 20005-1209

with full power of substitution and revocation, to prosecute the applications and to transact all business in the United States Patent and Trademark Office connected with these patent applications and issued patents.

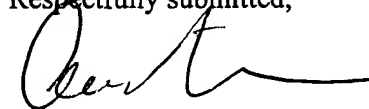
All correspondence regarding these applications should be sent to JOHN G. SMITH at:

Customer Number 055694
DRINKER BIDDLE & REATH LLP
1500 K Street, N.W., Suite 1100
Washington, DC 20005-1209

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patents, applications or any patents issued on the applications.

Respectfully submitted,

Date: 20/6/2007



BIO-MEDICAL RESEARCH LTD.
BMR House
Parkmore Business Park West
Galway, Ireland

EXHIBIT K



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent in the name of Michael Conor Minogue, et al. :
Ser. No.: 09/902,287 (now US 7,069,089) : US Class: 607/149
Filed: July 10, 2001 (Issued: June 27, 2006) :
For: ABDOMINAL BELT WITH ADJUSTABLE : Attorney Docket No.:
ELECTRODES : 200415-0001-00-US (404536)

**REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 C.F.R. §1.323**

Sirs:

Transmitted herewith is a Certificate of Correction (PTO Form SB/44) for U.S. Pat. No. 7,069,089, issued June 27, 2006. Correction is respectfully requested. Correction is required due to Applicant error. The required fee under 37 C.F.R. §120(a) is enclosed. If any additional fees are due, please charge deposit account 50-0573.

Corrections

On the cover page of the patent, please amend to read:

Foreign Application Priority Data

Jan. 11, 1999 (IE) S990016
Jan. 11, 2000 (PCT) PCT/IE00/00004

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)	
I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
BY	<i>Patricia H. Herrera</i>
DATE	<i>March 4, 2010</i>

Remarks

The corrections requested under 37 C.F.R. § 1.323 are made to correct a mistake of a clerical nature. The corrections requested do not materially affect the scope or the meaning of the claims in the issued patent and, as such, the corrections do not constitute new matter or require reexamination.

Summary

Correction of the patent as set forth herein is hereby requested. Patentee believes that the above errors are of such a nature as to justify the issuance of a Certificate of Correction.

Respectfully submitted,

MICHAEL CONOR MINOGUE, *et al.*

By:



ARMANDO A. FLORES

Reg. No. 41,754

Customer No. 23973

DRINKER, BIDDLE & REATH LLP

One Logan Square, Suite 2000

Philadelphia, PA 19103-6996

Tel: (215) 988-2819

Fax: (215) 988-2757

Enclosure: PTO/SB/44 (Certificate of Correction)

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**Page 1 of 1

PATENT NO. : US 7,069,089
APPLICATION NO.: 09/902,287
ISSUE DATE : June 27, 2006
INVENTOR(S) : Michael Conor Minogue, et al

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page of the patent, please amend to read:

Foreign Application Priority Data

Jan. 11, 1999 (IE) S990016

Jan. 11, 2000 (PCT) PCT/IE00/00004

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Armando A. Flores, DRINKER, BIDDLE & REATH LLP, One Logan Square, Suite 2000, Philadelphia, PA
19103-6996

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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